Establishing an Essential Medicine List for the State of Kuwait

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Establishing an Essential Medicine List for the State of Kuwait

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Abstract

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Keywords: Essential Medicine List, Rational drug use, Pharmacovigilance, Transparency, GCC health profile and economy, Standard Treatment Guidelines, selection criteria.

The Health Sector at the state of Kuwait is facing many challenges. One of which is public expectations in health are high, and thus, the Ministry of Health (MOH) in Kuwait has amplified the health expenditure by 86% since 2007. And since the medicine budget represents half of the total MOH budget, it is proposed that the development in health policy might be a suitable tool to control the inflation within the health budget. This thesis examines the opportunities and challenges of introducing an EML in Kuwait and the factors influencing its effectiveness. A mixed-methodology approach has been used to enhance and validate the data, in the form of interviews, comparative studies and questionnaires. One major limitation to the research was the lack of previous data relating to this work, and the information should be gathered in person in the form of hard copies, and later, the data was analysed using qualitative and quantitative approaches.

It has been attained that, the EML might be a valuable tool if adopted and implemented appropriately, EML adjustment to country health situation is crucial for successful utilisation and fulfilling the concept objectives.

Standard Treatment Guidelines are fundamental part of EM selection process, in Kuwait there were lack in the uniformity of the local STG, but fortunately, there is an eagerness to innovate, and the medicine situation might benefit from a type of organisation, overall, if the EML implemented efficiently in Kuwait, it might help in improving the general health and control the inflation in MOH budget.

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Acronyms

Acronym	Definition
ADR ……..	Adverse Drug Reaction
AFRO…….	WHO Regional Office for Africa
Alma Ata conference……	International declaration underlining the importance of primary health care
AMR……	Antimicrobial resistance
AMRO……..	WHO Regional Office for the Americas
CCS……	Country Cooperation Strategy
CMS ……	Central Medical Stores
DOI……	Declaration of Interests.
DTC……	Drug and therapeutics committee
EMEA……	Europe, Middle East, and Africa countries
EML……	Essential Medicine List
EMP……	Essential Medicines and Pharmaceutical Policies Department
EMRO……	WHO Regional Office for the Eastern Mediterranean
EURO……	WHO Regional Office for Europe
GCC……	Gulf Co-Operation Council
GDP……..	Gross Domestic Product Final consumption + Gross capital formation + net export
GNI……	Gross National Income
HIV/AIDS……	Human immunodeficiency virus/Acquired immunodeficiency syndrome
INN……..	International Non-proprietary Name
JUST……	King Abdullah I Hospital
K.S.A……..	Kingdom of Saudi Arabia
NICE ……..	National Institute for Health and Clinical Excellence
Me`dicins Sans Frontie`res.	An international, independent organisation for medical humanitarian aid
MeTA……	Medicines Alliance
MOH……..…	Ministry of Health
Mortality Rates…….	Based on number of deaths registered in a country in a year divided by the size of the corresponding population
MRA ……	Medicines Regulatory Authority
NFC……	National Formulary committee
NGO……..	Non- Government Organization
NGO…….	Nongovernmental organization

NHP……	National Health policy
NHP……	National Health Plan
NMP…….	National Medicine Policy
OECD……...	Organisation for Economic Co-operation and Development
OR…….	Operations Research
Orphan Medicines……	A pharmaceutical agent that has been developed specifically to treat a rare medical condition
OTC……	Over-the-counter
P3……	The pharmaceuticals partnership program (Australia)
PBAC……..	Pharmaceutical Benefits Advisory Committee
PBS……..	The Pharmaceutical Benefits Scheme
PSP……..	Public Sector Procurement
RDU……	Rational Drug Use
RMS……	Royal Medical Services
SEARO.....	WHO Regional Office for South-East Asia
Seattle WTO meeting……..	World Trade Organization Ministerial Conference
STG……..…	Standard Treatment Guideline
TNC…….	Transnational corporations, a parent enterprise are defined as an enterprise that controls assets of other entities in countries other than its home country, usually by owning a certain equity capital stake.
TRIPS agreement…….	Agreement on Trade-Related Aspects of Intellectual Property Rights
U.A.E……..	United Arab Emirates
UNFPA……	The United Nations Population Fund, formerly the United Nations Fund for Population Activities
WHO……..……..…	World Health Organisation
World Health Assembly…..	The supreme decision-making body of WHO
WPRO……	WHO Regional Office for the Western Pacific
WTO……	World Trade Organization

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Chapter 1

INTRODUCTION

1.0 Introduction

The collaborative work of healthcare professions is aimed generally in one direction, to provide the best possible healthcare services to all of the population. The prescribing and dispensing of medicines, the work of the healthcare professionals, the operation of healthcare facilities and the use of diagnostic tools should all be designed to work in collaboration. However, to do this they all need to work in harmony and connect together, otherwise they are likely to cause incomplete levels of healthcare and the patient consequently may not receive the full healthcare support which is needed and thus may not fully recover. For this reason, there should be development of the programme to use the Ministry of Health's budget efficiently and they should consider all aspects related to healthcare, through planning the use of the budget and the funding from a government, rather than spending most of the budget on just one aspect, which could result in another part suffering and lead to an overall inappropriate healthcare service. In some cases, where governments and health ministries have been shown to over-spend on one aspect, the tendency is often that in the next period, in order that other aspects of healthcare will not suffer, there is a tendency to compensate by increasing the request for a higher health budget. For this reason, a large debate often occurs at government ministerial meetings which try to assess how much should be spent without being excessive or going the other way and being insufficient (Waddell, 2010).

The World Health Organisation (WHO) during World Health Assembly meetings acknowledged this situation arising and has made suggestions on what is considered as appropriate health expenditure. In 1981, the WHO first made a recommendation and stated that countries should consider spending no more than 5% of national income on healthcare services. Following this proposal, Savedoff, in 2007, discussed the issue further and debated in more detail the question of how much a country should be spending on Healthcare Services (Savedoff, 2007).

In his proposal, Savedoff suggested that a country should firstly consider the overall financial position of a country in accordance with the per capital health spending and that they should take this into account, alongside the WHO statement that 'countries should spend, not more than 5% of national income on

health care services' (Savedoff, 2007). However, Savedoff suggested that there was still some confusion around the 5% figure and that it only appeared in WHO documents in 1981 as an indicator, that should be monitored, but not as a strictly recommended level of health spending. He suggested however that in recent years it may be the case that researchers, journalists, and policymakers have transformed this figure into a firm recommendation.

The 5% figure is however being regularly surpassed in many countries and the question which should be answered at this stage is why the growth is still rising? However from knowledge gathered it can be suggested that the answer is far from being straightforward, because healthcare is a very complex system, and is known to be governed by multi-factors. It is proposed that it can involve not only the budget of the country but also the life-style and the expected standards of living of the population, the quality of the healthcare providers, the standard of the healthcare facilities and what diagnostic tools are available and in operation within a country. It is proposed that all these aspects should work in collaboration to enhance the health of the population. But in introducing an improved Healthcare System there is the possibility of increasing cost. But it is expected that through increased efficiency in service and reduction of health issues increased costs can be controlled and may be reduced in the future.

Fig 1.1: Satisfactory Healthcare Chart

Source: created by author based on data from the WHO

The diagram above is one way of summarising what aspects need to be available to provide a satisfactory health service. But a major key point is having suitable financing in place, to ensure aspects of health and living are up to the standards expected in the country. From this financial basis, a country can have reasonable resources to include quality medicines, good regulatory control, and choice of medicines. These are likely to give a good impact on the efficiency of the diagnostic tools and the healthcare facility quality, and of course it is likely to ensure that the patient will receive high quality medicine. But in practice, unfortunately, that is not always the case, as it has been suggested by a number of agencies including the WHO that more than 50% of medicines worldwide may be being prescribed, dispensed, or sold inappropriately (WHO, 2015).

An approach has been suggested by Hogerzeil (2004) in an attempt to come up with solution to control a medicine budget and provide good prescribing practice. His suggestion was that the more affluent and countries with gross national income (GNI) of more than $12,476, should follow in the footsteps of the less fortunate countries, and adopt a more systematic way of controlling the cost of medicines. He suggested that this is important to prevent a future uncontrollable increase in health cost leading to a crisis in health management. It can be suggested from past evidence to be a reasonable approach but it needs to be borne in mind that each country's experience is unique to that specific country and a careful deliberation needs to be adopted in a suitable manner. It is considered important when looking at the escalating health budget to look at the reason behind this increase and try to locate the source of inflation, whether it's using too expensive medical technologies, over prescribing or even the tendency to preferentially prescribe a newer more expensive medicine. This medicine may not have established an advantage to other previously available medicines. From this short overview, it can be seen that there are many other sources of health fund drainage and as a result each country that have an interest in rationalisation should approach changes carefully (Hogerzeil, 2004).

Hogerzeil, 2004 in his study also suggests that there are a number of

alongside an increase of medicines cost. Taking one of the developed countries as an example in the SCRIP report which is an English International Pharmaceutical news, analysis and data service no (1974:21) it is indicated that there was an increase in medicine cost by 93% between 1987 and 1993 in Canada. It is then stated that 33% of this increase was due to the medicine price elevation, 15% due to increased quantities of medicines dispensed per prescription, and 55% was a direct result of prescribing new medicines (SCRIP, 1994).

From this report, it can be suggested that medicines can play a major part in increasing the healthcare budget, and control of this part of the budget is very important when developing Health Policy.

In providing a basis for a Policy this major issue can be tackled by carefully observing other countries methods in controlling the limited health budget that is available.

In developing and low income countries it has been proposed that, because of the limited financial resources, the predicament has always been how to get the best medicine with reasonable quality within the limited budget available. As an indicator it has been reported that this approach was followed by many developed and high income countries, as a mean of controlling the inflation in health expenditure. Typically Australia developed the practice of pharmaceutical reimbursement (Drummond, 1992), which is based on a limited list of medicines and also around the same time the United States of America introduced a restricted list of medicines for reimbursement (Lipton *et al*, 2000) (Gold *et al*, 1995).

In 2006, according to a publication by the WHO referred to as Contact (No 183, 2006), developed countries, were shown to spent roughly between 10% and 20% of their national health budget on medicines and in contrast developing countries, the range was higher and was shown to be between 20% and 40%. This development in spending of a high percentage of national income on healthcare has been noted by the OECD (Organisation for Economic Co-operation and Development), across the world. According to OECD (2011), the growth of health spending, which includes spending by both public and

private sources on medical services and goods, public health and prevention programmes and administration, (OECD, 2011) has suggested that spending has risen faster than the average GDP over the past 50 years. According to their figures it escalated from 4% of GDP in 1960 to 17% of GDP in 2009 (OECD, 2011).

In practice the actual percentage of a country's spending on healthcare does vary; as is shown on the following chart which represents Total Health Expenditure as a share of GDP in 2009 across a range of countries (OECD 2011).

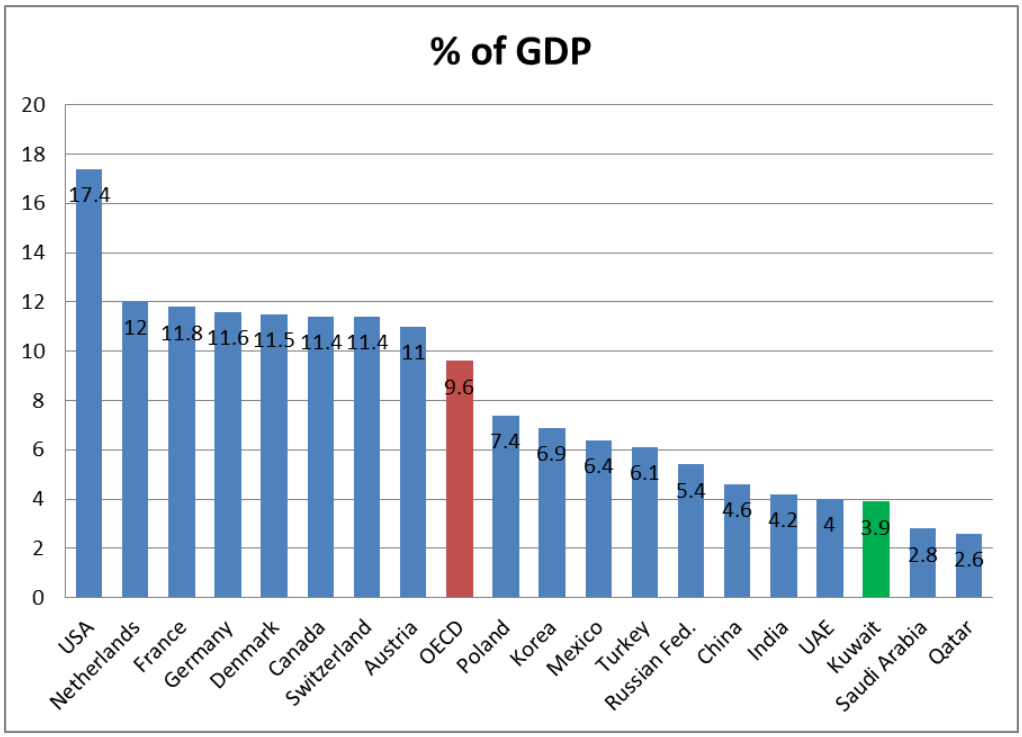


Figure 1.2: Total health expenditure as a share of GDP, 2009 (or nearest year)
Source: "Health at a Glance 2011: OECD Indicators- © OECD 2011"

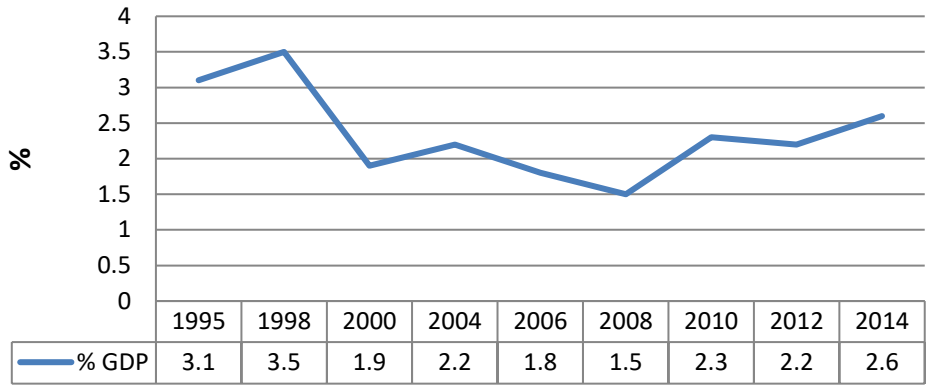
The figure reveals that the USA spends over 17% on Healthcare, which can be explained partly by the various insurance schemes that are available to the public that allows physicians to prescribe more expensive treatment regimens, if the patient is covered by an elite health insurance scheme. There was a study in 2013 conducted by the Commonwealth Fund which however revealed that spending a large amount in healthcare in the USA did not necessarily provide better health to the population. The report indicated at that

time that the USA had the worst outcome in chronic diseases, obesity and infant mortality in comparison to the other high income countries that have undergone the study (Squires and Anderson, 2015). The report demonstrated that in the USA the patient receives an average of 2.2 medicines per prescription and that could contribute to higher spending on healthcare, alongside other reasons.

Therefore, the presence of these reports appears to indicate that over prescribing of expensive medicines does not necessarily guarantee good health. It can be proposed that a certain level of investigation into the source of funding wastage and the strategies which should be implemented to review and address this wastage of health and financial resources should be carried out to try to come up with solutions. Such solutions could aim mainly to enhance the general health and provide a reasonable and practical control over spending. This situation is similar to Kuwait's Healthcare situation; because Kuwait is a country with excellent access to all kind of health-related resources and large fund availability. But unfortunately, it suffers from the lack of good managements of these resources and funds, as has been discussed earlier and it became clear following the study conducted by the Commonwealth Fund that the availability of cutting edge medical technologies and expensive medicines does not indicates better health and doesn't guarantee good utilisation of these resources. With this comment Kuwait total health expenditure as a share of GDP is low, it is only 3.9%, explaining this figure is not very easy because of the lack of data related to Kuwait and the lack of evidence to support this information.

The following figure demonstrates the fluctuation of Kuwait's Health expenditure as a percentage of the total GDP from 1995 until 2014, sourced from the World Bank Publications, it is apparent that in the nineties the total health expenditure was higher than what it is currently then it went down in the beginning of the millennium and started increasing again slowly (world Bank, 2015).

Figure 1.3: Kuwait Health Expenditure, Public (% of GDP)
Source: based on data from Kuwait Health publication, 2015



	1995	1998	2000	2004	2006	2008	2010	2012	2014
% GDP	3.1	3.5	1.9	2.2	1.8	1.5	2.3	2.2	2.6

The situation can be partly explained that the fluctuation is based on what the Kuwait Ministry of Finance allocates to the MOH, and as a result the MOH needs to work within this budget, however there are some exceptions when the budget requires intensification, but that is a different process.

In the previous discussion above relating to the Commonwealth Fund study, the position in the USA and Australia is referred to. But to get a balanced viewpoint it should be worthwhile to look at the attempts made by other countries with lower levels of funding for health resources and try to extract suitable indicators. These could be considered for Kuwait and it would be beneficial to try to find successful countries, where it has been used to control their health budget, and could be considered for implementation in the outcomes of this research.

As shown in figure 3 mentioned above, the overall cost of medicines can be high and therefore any developments in restricting the List of Medicines could generally benefit a Health Service. Therefore, it is proposed that there is an urgent need to control medicine use and promote rational drug use, which would lead to improved medicine access and decreased cost. This in turn could lead to important decreases in morbidity and mortality. It is proposed that the main way to have a better management of the healthcare situation is to implement a well-established and tested policy; where the strategy should be to aim to improve rational drug use, promote cost effectiveness and accommodate the health needs of the population.

However, it is important to be realistic and flexible and within a country it is important to ask whether a country should have a structured Medicine Policy? The response could be that a well-organised policy gives a framework for healthcare professionals to work within, in order for them to achieve adequate patient oriented care, to bear in mind the quality of the services provided and have a well-balanced budget (WHO, 2016).

The programme for Essential Medicine Lists, which was started in 1977 after discussions at the World Health Authority's meeting was then taken up by the WHO, It is a good example today of a structured, time-tested system that can provide the accurate requirement of medicines that satisfies the health needs of a population.

It is over forty years since the World Health Assembly discussed the need for recommendations of an organised 'list of medicines' and proposed this should be investigated further. The history behind the current list started in 1975 when Resolution WHA28.66 from the World Health Authority instructed the WHO to assist countries in the selection and procurement of essential drugs. The first list was published in 1977, but it faced criticism from prescribers because it suggested restrictions on some medicines which were in countries and commonly in use. But in 1978 the Alma Ata, Kazakhstan conference confirmed the agreement for the importance of the Essential List concept and in 1981 it was recognised as an important management requirement by the first edition of *Managing Drug Supply*. (R. Laing *Et al* 2003).

1.1 Aims:

The aim of this research is to examine the opportunities and challenges of introducing an EML in Kuwait and the factors influencing its effectiveness.

To achieve this aim, the following research questions have been formulated:

1.2 Research Questions which should be answered are:

- What is an Essential Medicine List and why do countries need it?
- What are the characteristics of an effective EML Programme?

- To what extent have other countries succeeded in their implementation of an EML?
- What are the contextual factors in Kuwait which would assist or hinder effective implementation of EML?

1.3 Study objectives

- Identify the concept of the Essential Medicines.
- To find out if it is possible to implement the EML concept in Kuwait.
- What might be the required steps to introduce it successfully.
- An attempt to detect the source of drainage in relation to the medicines budget.
- Try to recognise other beneficial characteristic for the EML concept, such as the reorganisation of the medicines situation in the Kuwait Public sector, it might promote rational drug use, increase patient trust and confidence in the healthcare services at the state of Kuwait and to promote healthier population.

Chapter 2

Critical Literature Review

2.1 Introduction to Literature Review (LR) Methodology

The review was carried out to extract knowledge on the subject of Essential Medicine Lists (EML) from the literature, to try to understand the importance of an EML and the basis of setting up an EML and summarising the impact an EML can have in a constructive manner. The LR was carried out in a systematic manner and focused on research questions, which would try to identify the basis of EML's, evaluate their value and to examine relevant and high-quality studies that were available and related to the topic and the research questions. The purpose in mind while conducting the LR would be to present the value of an Essential Medicine List and relate the concept of the EML to past and present experiences, then to introduce the fundamental elements of the PhD research programme and link this to Kuwait's health profiles.

The LR would attempt to focus on giving an unbiased approach, by reviewing the work of many researchers from different countries and from different backgrounds and to try to make the approach as thorough and transparent as possible. The LR was carried out at the very early stages of the research and was carried on throughout the research period by adding new material. By doing so, it was proposed that it would enhance the methodology and contextualise the findings.

It was conducted in a systemic manner to increase efficiency and reduce time consumption. This meant, basically, that the literature review focuses on the studies and previous research, related mainly to an EML and to Kuwait's health profile and includes examples from other neighbouring countries that have a similar health profile to Kuwait's and already have an established EML.

2.1.1 Time Frame of Literature Review (LR)

It was started in early February 2013 and continued until the end of the research; in total the LR work was concentrated on the first year, and then carried on parallel with the research.

2.1.2 Aim

To identify information regarding:

- Past/present Essential Medicine List programmes in similar countries.

- The elements and criteria, of an Essential Medicine List.
- Exploration of each criterion associated with the EML.
- The relationship between Kuwait and the Gulf Co-op Council in terms of the demography and health indicators.

2.1.3 Purpose of the Literature Review

The LR was conducted; in order establish why is an EML is needed, to become more acquainted with all elements of an EML. This could include aspects such as the history of the EML, when was it started, who launched the idea of an EML, who has adopted EML's, and has the EML or generally a restricted medicines list been a success.

It was expected that as the LR search progressed, there may be an opportunity to find information on whether the EML concept has expanded with time and how has the selection criteria on the EML evolved or remained the same.

Through studying the literature from the LR it could lead into an explanation of the popularity of the concept and whether there has been an expansion into many countries, worldwide. The LR may demonstrate the advantages and disadvantages of an EML programme and give an insight into what hindrances might be expected when starting the programme. In addition, it could explain the evolution of the list from 1977 until its current form today. Each concept of establishing a list, which needs to be considered when launching the programme, would be reviewed.

As the overall major research aim, is to discuss the basis for introduction of an EML programme for the State of Kuwait, in developing the background to the programme, it was considered vitally important to research into the basis of the health sector of Kuwait and the surrounding countries that share a similar health profile to that of Kuwait. An example is the countries which make up the GCC countries, this is an abbreviation for the Gulf Co-operative Council which is a political and economic alliance of six Middle Eastern countries—Saudi Arabia, Kuwait, the United Arab Emirates, Qatar, Bahrain, and Oman. The GCC was established in Riyadh, Saudi Arabia, in May 1981, the GCC countries that

were studied are the ones with an Essential Medicine List. In the LR the health burdens experienced by the GCC region would be considered, as well as the health cost, health budget and expenditure, and the demography of the GCC region.

2.1.4 Key Words

Several key words been used to research the literature, the following list represents them;

- Essential Medicine List.
- Rational drug use.
- Pharmacovigilance.
- Transparency.
- GCC health profile and health economy.
- Standard Treatment Guidelines.
- Essential Medicines selection criteria.

2.1.5 Search Protocol

Many search engines and scientific website that published related articles were included in the LR research the following is the list of the site being used for the research;

- Google Scholar.
- Pubmed/Medline.
- Athens/SCOPUS/Sciverse/Bradfinder.
- WHO site.
- GCC library.
- Arab Planning institute (Arabic language search).
- National Electronic Library for Medicines.
- ISI web of Knowledge.
- Global Health.
- International Pharmaceutical Abstract.
- CoChrane Library.
- CINAHL.

- World Bank Web.

2.1.6 Date of Search

Ranges from 1975 until the research thesis submitted.

2.1.7 Language of Search

The search language was mainly an English and Arabic search, but there was important requirements to include a few articles in French which are translated into English using google translate, the reason is because in countries like Morocco, Tunisia and Algeria, the official language being used and dealt by the majority of the population is French.

2.1.8 Exclusion Criteria

The first criterion for exclusion was based on the irrelevance of the title to the LR research questions, some titles did not includes the EML as a main topic and only included small section in the article itself, therefore, such articles have been excluded, there were a large number of articles that were excluded based on the fact that they appeared in more than one journal, Many articles were excluded because when going through them they were irrelevant to the concept of the EML and introduced no significance to the LR. Another exclusion criterion was based on the fact that some journals were inaccessible or required a very expensive subscription fees to access them, and Journals that were published in different languages other than Arabic, and English were also excluded, except as indicated above a few articles in French that required google translate to explain literature relating to the North African Arabic countries were written in French.

The following diagram represents a brief indication on how the LR was conducted.

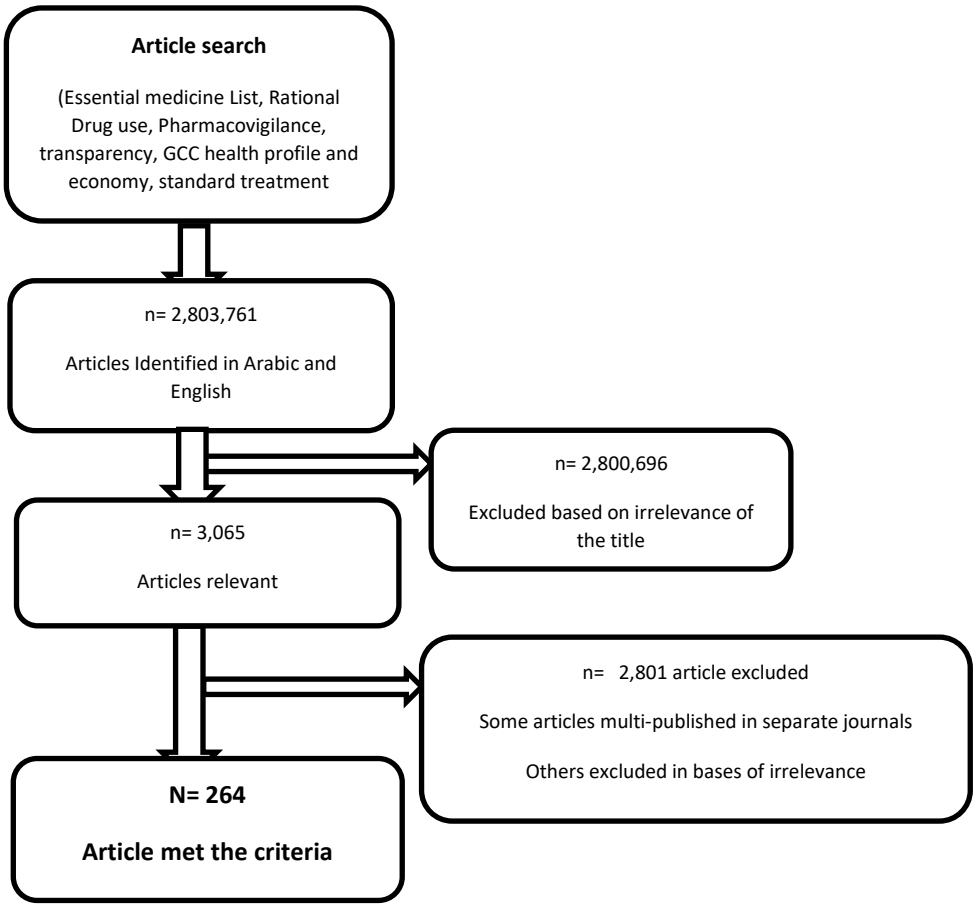


Figure 2.1: Exclusion and inclusion criteria in the literature Review

The references that met the required criteria of the research were close to 300 references, they were in published journals, government publications and books.

Most of the references relating to the concept of Essential Medicines List were sourced from the WHO library, few were published by various researchers in the field, a large number of the figures, percentages and statistics were sourced from the World Bank, the WHO surveys, and each individual countries official government Data.

2.1.9 Limitation of the Literature Review

Information in relation to Kuwait's healthcare situation were very limited, and very few studies have been conducted to explain the actual healthcare and medicines situation in Kuwait. A similar situation was noted in other Gulf Co-Operative Countries and for this reason the information was collected in person through field-trips to the countries from various government departments.

Another limitation was related to the language, and as there were a few related articles published in French and it took a very long time to be translated.

2.2.0 The Essential Medicine List

The Essential Medicine List, programme as first proposed in 1977 by the WHO, is still discussed and developed in the similar initial manner when it's first launched, with regular meetings of the medicine selection committee every two year, and from experience and knowledge it appears to be a good example today of a time-tested system that provides the efficient method of proposing a suitable List of Medicines that can satisfy the health needs of a population. The WHO EML concept has initially targeted countries with limited resources and poor medicine access; the EML's were published as a starter point and as a guideline to aid these countries. The list was never meant to be adopted in the exact form and adjustment is key, to be able to adopted a successful EML, and work and research is required to establish whether the EML concept is suitable to a certain country's healthcare situation, and further research is required to try to discover the most appropriate adaptation method.

2.2.1 Essential Medicine List

A strong healthcare system would not be considered a success without adequate availability of medicines. To ensure a well-established Medicine Supply Policy many factors are involved, from appropriate human resources, sustainable and logical financing, co-ordinated healthcare partners and institutions, and a comprehensive information system. These aspects are discussed more fully later in this Chapter, along with information on the development tools suggested by the WHO which could be appropriate in some cases to assess medicine supply (WHO, 2012).

It is proposed that a limited range of carefully selected Essential Medicines appropriate for each country can lead to better health care, better drug management and lower health costs (Hans V. Hogerzeil, 2005). This statement proposes that if there is a means to have a practical number of reasonably priced medicines to prescribe to patients, this might results in better prescribing practice in terms of assessing the quality of medicines more efficiently. This could ensure enhanced supply of these medicines and better patient access to them, the cost would be known beforehand, and all this could lead to a better and effective fund control. The number of medicines that can

be considered as being essential would then be related to a specific country health setting and needs. The cost of these medicines would be related to health needs and cost.

In terms of the number of drugs/medicines proposed by the WHO in the Essential Medicine List programme which started in 1977; it identified 208 individual medicines which they suggested together could provide safe, effective treatment for the majority of communicable and non-communicable diseases (WHO, 2013). It was proposed to keep it up-to-date with these medicines by introducing new and possibly more efficient medicines, by revising the list every two years. One of the programme aims is to improve access of medicines to all patients. But the medicines need to be of proven quality, they should be affordable, and suitable to the health needs of the population.

It is however, in reality a delicate process and requires a careful and thoughtful system of choice. When the WHO first introduced the list, it gave a model guide to what medicines could be considered as essential medicine but in practice the final decision lies in the hands of the local healthcare workers to decide what is suitable to the health needs of the population. But it was suggested there should be a reasonably high level of relative cost-effectiveness.

One point that has come out of the early literature and assessment studies in this research is the very important consideration in the assessment of medicines that the individuals responsible for Essential Medicines selection should have a wide knowledge of health issues and medicines generally and that they should be chosen carefully and their proficiency and knowledge is very important in ensuring the delivery and a suitable and successful selection process.

In these respects the WHO Model EML has been a good starter point for many countries, but it is pointed out through this background searching and research that individual countries health requirements varies respectively, and what is appropriate to one country health situation might be irrelevant to another. Therefore following the WHO guideline precisely and attempting an exact implementation of the WHO Model EM List was found early in these

studies not to be appropriate and best practice, and might have a reverse effects and worsen medicine access rather than enhancing it, especially that the WHO EML is designed to countries with poor sanitation and low standard of livings that results in more medicines to treat diseases such as malaria, tropical diseases and infectious diseases. This situation is not applicable in countries like Kuwait, because Kuwait has a high income and has good access to quality housing and clean water and food, and has a good standard of living. From the early studies, some general points of concern to health in Kuwait is related to the inflated medicine budget and the lack of skills to appropriately manage the MOH general Budget and the Inflated medicine budget.

An important consideration need to be acknowledged and considered when attempting to select medicines, is the racial variances. Ethnicity is one factor that may account for the observed differences in both pharmacokinetics (PK) and pharmacodynamics (PD) of drugs, resulting in variability in response to drug therapy (SU Yasuda, 2008). The following table describes some examples of the variances in medicine potency in regards to the ethnicity variation.

Table 2.1 : Examples of the effect of the ethnic differences in allele frequencies for selected enzymes, transporters, and pharmacologic targets

Enzyme	substrates	Alteration in function	Allele frequencies (%)			
			White	Black	Asian	Chinese
CYP2A6	Nicotine	Reduced or virtually absent	0.7	1.1	-	0.4
CYP2B6	Cyclophosphamide Efavirenz Nevirapine Bupropion Methadone	Increased	6	2	4	-
CYP2C8	Repaglinide Paclitaxel	Reduced	0.4	18	-	-
CYP2C9	Warfarin, Phenytoin Tolbutamide	Reduced	10 13.3 14.9	3 1 3.6	Absence	-
CYP2C19	Omeprazole Diazepam	Non-functional	13.6 15	17	-	29.7

Table sourced from SU Yasuda *et al,* 2008

To examine Kuwait's Healthcare position, it was important to have the correct background information to the country's healthcare situation and the actual fund that is required to support this concept. Also, to examine and consider the level of competency of the human resources that would carry the concept forward. It was therefore considered important to clearly identify all the relevant aspects that are required to implement a suitable and relevant policy. In this regard, Kuwait's Healthcare situation is rather unique because Kuwait it appears to have the capability to fund the healthcare services fully. But from the early studies and from personal experience of working as a senior pharmacist in the public sector it may lack the suitable organisation and competent expertise and the professional skills to run the healthcare services efficiently, which may be revealed in the research undertaken.

For these reasons, it was considered important to establish a full knowledge of the healthcare system and situation in Kuwait and to gain good skills to examine the concept of EML and try to view it from several prospective. By doing so it was expected that it would help in accurately establishing how suitable this concept would be to Kuwait's healthcare situation.

At this point it was considered to be useful to attempt to understand an Essential Medicine List fully and try to view whether the EML concept is suitable to Kuwait's Healthcare situation, by carrying a suitable level of research and knowledge to the implementation processes carried out by several international and also neighbouring countries, and this could be useful to finds ways in which this concept can be altered to suit Kuwait healthcare requirements.

2.2.2 Definition

The Essential Medicines are defined by the WHO as being

'Those that satisfy the priority health care needs of the population. They are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times, in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to

many different situations; exactly which medicines are regarded as essential remains a national responsibility.' (WHO, 2002) (Hans V Hogerzeil, 2004).

The concept is however very general and doesn't explain any particulars, when the WHO indicates that the medicines are essential, there is no indication to the implication of this term and the method in which a medicine can be considered as essential or not, the only information given is the fact that the medicines should be related to the health needs of a population, this is a valid point but unfortunately, it is very broad and there could be a large number of medicines that treat similar illnesses, and the cost can be closely related.

The definition indicates that a medicine would be considered as being essential if there is evidence of its quality and safety, again this notion is valid and important, but the concept and the actual lists when they were initially launched, was aimed at countries with limited resources. For instance, in many of the low-income developing countries, how such countries can ensure the quality of a medicines when there is no appropriate Quality Control and Quality Assurance laboratories to establish the quality of medicines is unclear. Furthermore, in such cases the cost would be high to retest and reassess the available medicines and to establish the quality of the newly procured medicines. This could be an added cost a country might need to consider if a country decided to adopt the Essential Medicine Concept. There are many such aspects which need to be considered in introducing an EML, as discussed more fully in the work carried out in this Thesis.

The definition also states that to make a proper medicine selection, it is important to consider the health needs of the population. This is another aspect which needs to be considered through this study, as it requires an efficient system of data collection to establish an accurate knowledge of the diseases pattern, and such processes. When an appropriate healthcare system does not exist, this knowledge is difficult to achieve, and the solution at this point might be that the selection committee will end up depending on their own initiative to figure out the disease profile, and this method will not be very accurate.

In other words, having a list of medicines doesn't always guarantee treating patients and giving better health, and the healthcare facilities may need

to be re-organised to provide appropriate treatments. Therefore, having an EML might enhance procurement practice, and might have a positive effect on prices and cost, the reason for this, is because when buying in bulk, the suppliers can give better price.

The initial reason for the WHO to come-up with the EML is to provide low-cost access to quality medicines for low-income countries, for this reason, only low priced medicines were initially included in the list. Currently the concept generally of cost-effectiveness has been introduced both by many countries of the world and in the WHO List and some expensive medicines are included due to the benefit/cost ratio, (such medicines are the antiretroviral medicines). It's been declared that antiretroviral medicines are essential to control the spreading of viral conditions, such as HIV, and should be on the national EML, where the health issue is of concern. The WHO Model EML, 2002 first included medicines for the prevention and treatment of HIV/AIDS (WHO EML. 2002).

When considering the EML concept overall, it is however defined slightly differently from country to country as the interpretation of the definition terms varies between countries and complies within individual countries where there are available funds to support the concept. This includes areas such as the health requirements and the clinical capabilities of each country, but overall the introduction of an Essential Medicines List as indicated above is a complex process requiring a considerable level of research.

But the groups-countries involved all seem to agree on the main outline concept, that the list should contain a manageable number of medicines with an established clinical relevance and proven quality, which are affordable at the standards of living of a particular country. In carrying this general definition through another of the early problems in choice of suitable medicines for a particular country was that information on post-market surveillance of medicines was limited and the information accessibility was often inadequate. But in the present times it is more advanced and accessible and for this reason the selection of medicines for the list moved from an experimental based system into evidence-based in the early part of this century (Report to WHO Executive Board, 2002).

Coming back to the WHO as an organisation it was established to assist particularly developing countries to introduce areas of Health Development. The WHO came about to give support to the poorer countries. In addition, it included in its support not only financially poor, but information poor countries, which may to a certain extent include some areas of health organisation in Kuwait, because Kuwait can be considered from some directions to be a developing country. These aspects will be part of the studies undertaken in this research Thesis and at the initial stages it can be proposed through experience that Kuwait may have a very high access to all kinds of resources but may lack the appropriate managerial skills to utilise the resources efficiently.

Whether this is the case, then the research study may establish or propose the need for adjustment/change, such as investigation into restructure and reinstate a more organised healthcare that might reflect positively on the general health and the general MOH budget. But these comments are only through work experience as a senior manager and are still to be established in this study.

Generally speaking, the basis for the introduction of an EML came about because it was clear at the World Health Authority Conferences that many of the Developing Countries had difficulty putting together Health/Medicines requirements and information from the information produced by other Regulatory Agencies, particularly in High Income-Developed Countries where the majority of medicines were/are discovered and developed and from the Pharmaceutical Companies on medicines which were appropriate for health areas such as tropical and obscure diseases. Access to low cost medicines know as Generic Medicines was also an issue, and required deliberation.

Initially, the EML were more appropriate to countries with limited income level, but in the recent years, EML changed and became more suitable to wider range of countries with various income levels.

The EML moved into a List more suitable to countries needs and for health and current diseases, financial position, Government strategies, educational developments, population changes and many other developments.

Therefore, the EML which is almost forty years old has been very helpful to many countries. The information about the Medicines on the List comes from the Companies, the developed countries and their Regulatory Agencies and increasingly from Databases to include the Uppsala Database linked to the WHO (and other Databases).

2.2.3 Essential Medicine List Progress

Countries with limited access to healthcare resources, has tried to come up with solution to enhance medicines access in a financially suitable means. The limited income countries realised that medicines are costing the country a great deal and medicines access was an issue, for this reason several countries tried to have a form of a list of medicines that is required by the general public, this is a form of a strategy to enhance medicine access and control medicine budget, one of these countries were Peru, in 1960 it created a list of basic medicines as an attempt to enhance medicines access, later in 1971 it started a basic programme to promote the basic list of medicines as a method of improving the general health and reduce cost (WHO, 2016).

Similar situation was observed in Tanzania in 1970, where the first non-official Essential Medicine List was created by Tanzania, and the country's Health Service directed their efforts in trying to enhance the medicine supply in their healthcare facilities, to control the expenditure and provide quality medicines. This attempt was carried out by the Tanzania Healthcare services as their own effort; the Tanzanian List of medicines was designed before the WHO launched the Model list of EM (Bartle, 2014).

Mozambique is another country that solely attempted to organise healthcare and medicines situation by creating a restricted list of medicines, the list was created few months prior to the WHO Model List of Essential Medicines, and according to a survey carried out by the WHO in 2006, stated that medicines access increased from only 10% of the total population in 1975 into 80% by the year 2007, the survey did not indicates whether this tremendous enhancement in medicines access can be referred to the efficient use of the

restricted List of medicines or due to some other strategies been adopted by the healthcare services in Mozambique (Medicines and health products, 2007).

The WHO started the processing of the first EML in 1975, and World Health Authority in 1975 (Resolution WHA28.66) called on the WHO to assist member states to select and procure essential drugs of good quality and at reasonable cost (Laing*, et al*, 2003).

Seven years after Tanzania launched their own national none-official EML, the WHO announced and published a list of 205 medicines and considered them as essential to general health needs. This publication however raised an accusation that the WHO, by announcing the EML, was trying to restrict prescribers from the freedom of prescribing. However, the list was welcomed by many organisations, and was considered as one of eight components of primary healthcare, this was identified by the Alma Ata conference in 1978. And the first edition of Managing Drug Supply identified drug selection as an essential management requirement in 1981. A year later Bangladesh adopted the concept (Laing*, et al*, Lancet 2003).

The World Health Assembly in 1984 gained further support for the EML concept from all the delegations, the USA had their own version know as Medicaid preferred drug lists since 1965, to provide healthcare services to low-income individuals (Kaiser Family Foundation Medicaid Facts, 2009), and in the case of the UK, they introduced a Restricted List of Medicines.

The philosophy of an EML was widely spread by 1991, and more countries adopted the idea of a list including NGO (Non-Governmental Organisations), however, there were still some concerns on the basis of justifying the medicine choices, and as a result the choices moved from just experience based choices into evidence-based submissions, and this was finally agreed in 2000/01, although the list were widely adopted by several countries, it still came with some issues, the model list is a good starter point but it requires several adjustments and changes to be suitable to a certain country healthcare situation, the adjustment requires in depth research and knowledge to the actual level of healthcare services and medicines situation, it is important to identify clearly the process of introducing a new concept or

policy, what is required to support a successful implementation process, the skill level and actual knowledge of the working power, it might be important to identify the funds that are available to support the policy or the concept, the selection criteria could be different than what have been suggested by the WHO, and this might be true due to the fact that Kuwait cost-effectiveness approach might differ than other countries, for this reason careful medicine selection approach and well-thought of adaptation plan is required, furthermore, it might be useful to identify the current health and diseases profile to support a successful medicine selection tactic.

In addition to increase access to medicines, suggestions were made at the Seattle, USA WTO (World Trade Organisation) meeting to subject the WHO EML to automatic compulsory licensing; this meant countries could manufacture medicines without seeking the consent of the rights holder, but instead pay the rights holder a set fee for the license.

With all these efforts to ensure a successful EML, discussion took place with the USA and others and the final version of the revised procedure was adopted by the WHO Executive Board in January, 2002. As a result a modified form was published. Several changes and additions to the EML were included, such as including several antiretroviral drugs under patency, alphabetical and anatomical therapeutic chemical (ATC) classifications and translations into four languages appeared within months, and the development of web-based EM Library.

In 2007, the world health sector, in general, and the WHO in particular, had noticed that children are more sensitive to some types of medications and require specific attention, for this reason the WHO published the first WHO Model EML for Children (EMLc). This approach is wise, kids requires special consideration, because they are still at the body developing stage and healthy kids will eventually results in a healthy and strong community.

The WHO now has a specific department to deal with the Essential Medicine List programme; this department is called The WHO Essential Medicines and Health Products (EMP). The objective of this department is to ensure the continuation of the concept, it aims to update it and keep it up to

speed with the continuous advances in medicine technology. Its main duty is to collaborate with countries to aid them in gaining reasonable access to quality medicine information and guide member states in the medicine selection process. The department was founded over three main fundamentals; access, innovation and regulations together with other duties such as education, training and technical support.

The concept of the Essential Medicine List has become popular and the work of the WHO is significant, which is evident because by 2008, 81% of the WHO members have a form of the Essential Medicine List and 65% of countries have updated the list in the past 5-10 years (WHO 2015). These figures indicates countries adopting the concept with modification to suit each country healthcare situation, but doesn't indicates the level of success of the implementation process and whether adopting the EML concept helped to enhance medicine access.

In the early years of the concept, the selection criteria was based upon experience (Laing. 2009), as the world developed and access to information became easily reachable, the selection criteria moved towards evidence based and post-market confirmation of medicine efficacy.

The WHO Essential Medicine List has gone through a lot of changes throughout the years; the following table represent the changes that occurred since 1998 until 2011.

Table 2.2: Deletion and Addition of Medicines on WHO Model EML

	1998	**2000**	**2002**	**2003**	**2005**	**2007**	**2009**	**2011**
Deletion	13	6	0	12	17	3	4	21
Addition	31	14	12	4	9	22	16	27
Duplication	50	51	52	52	57	56	81	87

Source: WHO website, WHO EML from 1998-2011

As it can be seen, changes do take place and it is considered important to keep the list updated, otherwise the list can become outdated and unsuitable to the current health requirements, this continues follow up of the medicines on

the EML and continuous updates might demonstrate the expert committee commitment and interest in keeping the concept of EML efficient and the medicines on the list are suitable to the advancements in the field of pharmaceuticals.

The concept when first came out and launched, it designed to help the less fortunate countries that has limited access to quality medicines, but years after the utilisation by the limited income developing countries, the more middle and high income countries became interested in the concept, and some of these countries has actually started following the footsteps of the less fortunate countries.

The EML as proposed by the WHO is not accepted as the best way of developing access to medicines in Kuwait, because Kuwait has the potential both financial and structurally to introduce a system that is specifically structured to benefit Kuwait patients. The WHO EML is a baseline, but Kuwait has bypassed the fundamentals of the WHO EML, the research aims in taking the underlying concept of the EML proposed by the WHO back in 1977 and producing an overall development programme based on an EML that provides Kuwait with medicines and health support , which is affordable, provides relevant medicines for the illness faced by Kuwait population, handles the public/ private interface, controls the introduction of medicines to Kuwait patients on clinical needs-cost effectiveness-medical-effectiveness program.

2.2.4 EML Concept in Relation to Higher Income Countries

High incomes countries are defined by the World Bank, as countries with are those with a GNI (Gross national income) per capita of $12,476 or more.

The developed countries and the high income developing countries such as the Gulf Co-operation Council countries are faced with new challenges in health; this is due mainly to diet and the sedentary life style that gave rise to modern life chronic diseases such as cardiac problems, cancer, respiratory diseases and some mental illnesses. Countries with good access to health resources ended up with more aging population and that resulted in old-age conditions that require more attention and care. This entire situation gave rise to an increase in health cost and more demands on healthcare and medicines.

Hogerzeil, 2008, support the previous discussion and has indicated in his study that the inflation of a medicine budget is generally due to an aging population, general elevation in medicine costs and the continued introduction of new medicines, which may have little extra benefit, but add to the overall high cost. In contrast the aim of a Ministry of Health in a low-income country is generally to obtain quality medicine with a suitable cost.

Currently the same concept is being adopted by mid and high income countries, as a tactic to fight the ever-increasing medicine costs. example of that is found in Australia and New Zealand, two countries with an advanced healthcare system and at some times in the nineties had the lest cost of medicines is currently faced with a rapid medicine inflation, and both countries took very strong measures to come up with solutions for the situation, one solution was to establish a national EML and bases medicines procurements and reimbursements on it. The success of this approach is yet to be confirmed, there are no significant studies or data to indicate the outcome of the utilisation of the EML concept in Australia and New Zealand (Clement FM et al, 2009) (Stafinski T, Menon D. 2003) (Lexchin J, Mintzes B. 2008).

If high income countries adopt the concept of an EML, the effect can have an impact on a variety of healthcare areas, including; the promotion of rational prescribing, more focused healthcare professional training and follow-up training. It can also lead to improved prescriber’s knowledge of medicines,

often because there may be limited medicines used, reduction in adverse drug reactions and this is achievable because the drugs on the list are better documented and acknowledged. In addition, there can be many other improvements in the medicine supply cycle involving procurement, storage and distribution, and when procuring large quantities of medicines this often results in price reductions. Overall however, the major advantage of introducing the concepts of an EML, can be that a country should have a continuous supply of medicines at all times, ensures patients have access to their own medicines, and these can lead to improvements in patient compliance, improved patient health, and as a result improvements in the overall health of the population (WHO, 2013).

Because of all the facts and suggestions mentioned above, it can be suggested that the Essential Medicine List has delivered more than it was initially suggested it would achieve, providing there is a proper follow-up and transparency in the procurement policy which practiced. Therefore the List might be beneficial in multiple areas not only in cutting cost but also in providing better healthcare, and that is a major requirement for any country and any community regardless of the standard of living and how wealthy it is.

In the state of Kuwait, the medicine budget is alarmingly high. The following table shows an actual breakdown of the MOH expenditure from 2006 until 2010.

Table 2.3: Financial data from the general budget department of the MOH Kuwait, (2005-2010)

Item	**2005/2006 (KWD million)**	**2006/2007 (KWD million)**	**2007/2008 (KWD million)**	**2008/2009 (KWD million)**	**2009/2010 (KWD million)**
Approved	470	555	639	1048	877
Executed	448	538	589	1020	837
% Executed	95.3	97.0	92.2	97.3	95.4
Expenditure per capital	143	158	172	213	230
% of MOH budget from the country budget	6.7	5.3	6.2	5.6	7.6

Source: Population Statistics – Public Authority of Civil Information

The next table represents the percentage of medicine cost to the Kuwait MOH total budget.

Table 2.4: The percentage of medicines cost from the total Kuwait MOH budget.			
Category	**Total amount in % 2009**	**Total amount in % 2010**	**% Change**
Drugs	52.6	59.5	12.3
Source: General Budget Department of the MOH Kuwait, (2005-2010)			

As is apparent, from the above two tables, the Ministry of Health budget has doubled and the medicine cost, that represents half of the MOH budget, has increased further, therefore employing some kind of control over the medicine budget will have a direct impact the general health budget, the table demonstrates that in the financial year 2008/2009, the MOH budget increased tremendously to over billion Kuwaiti Dinar that will be close to over 3.7 billion Dollar, this kind of figure could be considered as the total country Budget of some countries, there is another point needs to be considered when looking at these figures and budget costs is the fact that Kuwait population is little over 3 million only, and the MOH and Medicines budget is very high to this population size.

This kind of increase requires an immediate attention to control it, otherwise it reaches unrealistic and unaffordable figures, for this reason starting a protocol or a suitable policy to avoid reaching a stage when medicine becomes inaccessible, even in a high-income country like Kuwait.

2.2.5 EML in Relation to Standard Treatments Guidelines (STG)

Standard Treatment Guidelines can be defined from its name, but the precise definition can be quoted from Ghana STG 2010, which has been reported as being '*STG are systematically developed statements that assist prescribers in deciding on appropriate treatments for specific clinical problems. They usually reflect the consensus on the optimal treatment options within a health system and aim at beneficially influencing prescribing behaviour at all levels of care*' (Ghana STG 2010).

The purpose of a STG is to provide recommendations on the most constructive method of treatment for a particular disease, however it aims in no way to restrict prescribers or hinder their decision making. The overall aim of a STG is to assist prescribers in the choice of treatment, it helps with the training of new health professionals, gives patients a direction of how the treatment progresses which will improve patient/doctor relationships (NICE, 2013).

The relationship between, STG and EML should be fused together. Medicines on the Essential List should not be chosen without having evidence-based treatment guidelines to follow and knowing what kind of medicines are being prescribed to patients. Standard Treatment Guidelines need to be placed in accordance with the quality of the medicines and benefits/cost-effectiveness principle. Therefore, a successful, well thought-through, and functioning Essential Medicine List should be combined with a functioning and health situation profile related STG.

The STG and the EML are continuous processes and once the decision is made, and the guidelines and lists are published, the work should not stop at this point. There should be, regular monitoring, reviewing and follow-ups. In addition there should be continuous staff education to ensure an adequate knowledge of the STG and Essential Medicine List components (WHO 2002). Achieving this process can be done by employing a Standing Committee to include members from different health fields. For instance, the WHO recommends that members of the Committee should include doctors, nurses, a pharmacologist, pharmacist, public health workers, consumer affairs and health workers at the grass-roots level (WHO, 2002).

Another point which should to be considered when choosing the medicine is the strength of the evidence, for example ‘the result of a systemic review of clinical trials can carry more weight than the results of an observational study without controls, and should be much more than personal experience of individual experts’ (WHO. 2002).

The decision of medicine selection is complex, it’s not very clear and the guidelines that are set by the WHO are not straightforward. But this is understandable due to the fact that the concept of cost-effectiveness is relative,

and some expensive medicines might be considered as being an Essential Medicines due to the need character and the importance of a particular medicine to the general health and because of the lack of a more affordable alternative, this can be explained better in terms of antiretroviral medicines, although they are an expensive medicines but they are essential and its proposed to be important to have them in a functioning healthcare system (Hans V Hogerzeil. 2004).

2.2.6 EML Timeline

In 1977, the World Health Assembly endorsed a new strategy to promote all nations health, it's titled 'Health for All by the Year 2000' (F. Antezana & X. Seuba, 2008) the main objective of the strategy, is to find ways to enhance health; the choice of tools need to be suitable to the country concerned. The reaction to this resolution was the development of the WHO Model List of Essential Medicine, the development process started in 1975 but the first list was published in 1977. The programme was never be finalised that year, it kept being monitored, reconsidered, and improved (WHO. 2016).

1975 until 1982 is considered the establishing stage of the programme, it included launching the EML then getting adopted by the Alma Ata in 1978, until later the concept was modified in 1982 where the word Drugs in the title was replaced by Medicines, it's understandable when starting a new policy to have a stage where the system is more experimental and awaiting amendment, it's not totally accurate that any new policy when started was faultless and didn't requires modifications at a later stage.

In 1999, the medicine selection method changed the medicines from the selection based on the Expert committee members own professional and scientific experiences, into the available scientific and real life evidences. This needed to happen due to the large amount of research on post market efficacy of medicines and the pharmacovigilance programme that had been expanding worldwide and was adopted by many countries. This new approach for medicine selection didn't get picked up until 2002 (R. Laing *et al*, 2003).

The second phase of the EML programme is related to consolidating the programme and the concept as a whole; this is from the 1992 until 1987, there

were uncertainty to nature of the programme, it wasn't clearly defined at that time as whether it's a new unit, a very typical WHO programme or a policy, this was sorted and the EML is considered linked with the national Medicine policy (WHO, 2004), then the programme get implemented in Tanzania and adopted by UNICEF, in 1985 the Nairobi conference agreed that EML policy needs to be developed as a tactic to promote rational drug use (F. Antezana& X. Seuba, 2008).

The third phase was from 1988- 1994 and it was related to redefining, at this stage the duties of the EML committee moved to being advisory upon request by other countries, which limited the members at some level, but it had a positive impact which lead establishing education programmes.

The fourth phase was from 1995 until 2007, this stage can be considered as being very important at Economic, Technological and Social levels.

The following flowchart summarises the changes that the WHO Model EML went through over the years.

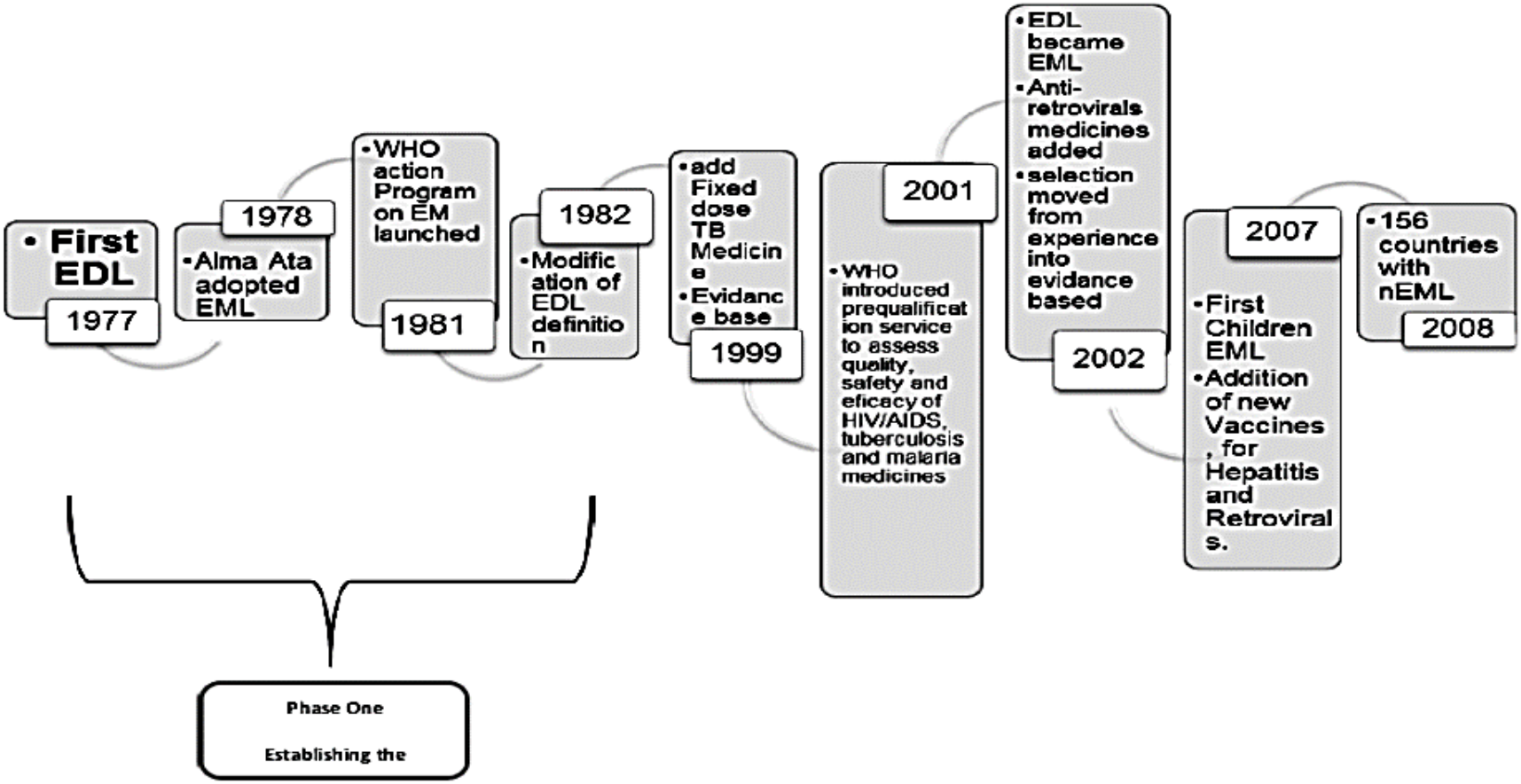


Figure 2.2: WHO Model EML timeline from 1977-2008
Source: created by author based on data from WHO website.

2.2.7 Challenges of developing an EML

As with any new concept that is introduced, concerns will arise when introducing the list and a careful well thought through process should be adopted to introduce the EML to the entire population and make it acceptable; it is a very delicate process and extreme care needs to be employed. It is proposed that all issues are required to be addressed and if possible nothing should go unresolved. In addition to the structure and operation of an EML, there is a need to establish an education programme to the entire population at different levels of details, in order that all of the population has the opportunity to become familiar with the EML.

There are several concerns that might come up if the EML concept been introduces, these concerns might be expected by both health care providers and healthcare recipients.

The Prescribers may see it as a way of hindering and restricting them from freedom of prescribing, where Pharmacists may see it as a way of reducing financial benefits, but the main concern might be expressed by the Manufacturers that fear that their market might become tough and competitive, on the other hand patients might think that they are getting lower quality medicines of a second class type, and this may lead to loss of confidence in the medicine and lower levels of compliance (WHO, 1988).

Overall, it’s worthwhile to get the concept explained clearly and makes it clear to all that the EML is not a list of cheap medicines; it’s rather a list of more quality and affordable medicines and a list that contains some medicines that are expensive but very important to the general health.

2.2.8 Essential Medicines Selection Criteria

The WHO has proposed a set of selection criteria which could be considered when designing National EML, but the proposals are only made as a guidance and it is clear that it is the responsibility of each country to set its own selection criteria that will benefit the wellbeing of the population and suites its needs.

The Model List of Essential Medicines is therefore provided by the WHO, as a guide to support countries in designing their own List that can be unique to their specific country and comply with the country's health needs and budget.

The WHO have in place an Expert Committee, which works towards revising and adjusting their list every two years and at the same time proposing guidelines as to why a medicine has been updated on their List, as an aid to countries who may want to use the List or parts of it. It is proposed that the revision and update is required for several reasons, which includes; the continuous advances in science and research, which are occurring on a regular basis. In addition, there are new discoveries in medicines and pharmaceuticals together with the availability and accessibility of post market evidence of quality and efficacy. All these developments might cause an alteration to the decision of medicines selection, some newer medicines might be better choices and some previously selected medicines might require deletion based on new evidence of quality level or lack of the required level of efficiency.

Another aspect of the adjustments to the EML produced by the WHO is the reformation with time of developments in Standard Treatment Guidelines (STG) for medicines that have been shown to be clinically valid and these aspects can be closely related to the selection process of the Essential Medicines on the WHO List. However, when a country proposes to introduce or continues to use medicines on the list they would normally do so after careful deliberation and study of this selection as the drug/medicines from the list should be appropriate for the needs of the population in that country. In order to assist a Ministry of Health to make this decision, the WHO can provide advice and help to the member countries in terms of their decision to select particular medicines. Furthermore the medicine selection processes is required to comply with the national official STG in the country, by following this step it will verify to the prescribers that their decision making is not impaired and been withdrawn from them, because they are following the national STG in their prescribing practice, the last statement demonstrate that since the STG are different from one country to another, and comply with the unique disease pattern to each country, the national essential medicines are selected in a similar manor and adopting the WHO Model EML is an unsuccessful practice.

Therefore, the value of the work by the WHO Expert Advisory Committee is in providing knowledge and evidence which can assist a Country's Ministry of Health by proposing procedures which could be followed in selecting, updating and eliminating medicines from a countries list.

In respect of the terminology used in the early definitions by the WHO Expert Committee it was decided that they would use the term Essential Medicines rather than Essential Drugs, in order to include a broader range of pharmaceutical preparations. In addition to these points in carrying through the selection of medicines for regular use in a country it was proposed by the Expert Committee that a country should consider adopting a systemic approach when introducing or deleting a medicine from the list.

These individual medicines are however part of an overall Policy and it is considered important in the general discussions surrounding setting up an EML or Health Policy in a country that there should be openness and transparency practiced. This is suggested to particularly be recommended when making a selection of medicines on a general list and in the medicine selection. For instance, the background and the medicines list could be accessible to all and should be discussed relatively openly. It is suggested, with these proposals, that they should be discussed, through a country's own Expert Panel/Committee and where possible a country should assemble a group of experts with a relatively wide range of background knowledge from various pharmaceutical and medical backgrounds.

It's been proposed by the WHO expert Committee to launch an Essential Medicine Library at an international level to help in accessing medical information to all healthcare providers (WHO. 2001). Currently the WHO has launched a wed-based information service and provides access to the WHO Model EML, it provides disease information and suggested treatment line, and it includes the WHO Model formulary.

Jordan is an example of a country which in 2006 considered its development of an EML, by using some of the procedures suggested by the WHO. It is also a country which has many similarities with Kuwait, and shares a similar health profile with minor differences and as will be seen later in the

discussion of the research programme, it was used as a comparator to aid the basis for the EML selection criteria for Kuwait. Jordan has, had an established EML, since 2006 and bears a close similarity to Kuwait. Its Essential Medicine Department is part of the Jordanian MOH and as indicated above it has developed the selection of Essential Medicines by taking note of the WHO guidelines.

The Jordanian Essential Medicine List (2006) (Jordan Rational Drug List V1, 2006) quotes that the Medicine Selection Process is based on the published disease patterns, and that the efficacy and safety of the selected Essential Medicines should be based on objective results from adequate pharmacological studies, and they should meet satisfactory quality control standards, including pharmaceutical stability and when necessary, bioavailability.

The overall patient cost of medicines is an important issue together with the total cost of the treatment regimen and that can include cost of combination of drugs necessary to accomplish the treatment regimen versus unit cost of each drug (Jordan Rational Drug List V1, 2006). This criterion is the difference between Jordan and Kuwait and this is the case because the income level in Kuwait is higher and the level of affordability is different between Jordan and Kuwait.

It is also reported that the Jordanian MOH Medicine Selection Committee (Jordanian MSC) considered during the selection process the capabilities of the healthcare providers to use, prescribe, administer, and monitor the safety and adverse effects of a single drug or group of drugs in a therapeutic category. In addition, Jordan also considered during the selection process, the influence of the concomitant, locally prevalent diseases or conditions, and the medicines pharmacokinetic and pharmacodynamics parameters, that might lead to a modification in the therapeutic response, e.g., malnutrition, liver disease.

The Jordanian Medicine Selection Committee (Jordanian MSC) reportedly made specific considerations to evaluate the benefit/risk ratio of the medicine undergoing selection, in their deliberations however the committee put forward for discussion several comparable drugs/medicines which had similar claimed therapeutic indication. After further discussion and gathering of data, it

was necessary to select the one that provided the most favourable benefit/risk ratio. These deliberations were able to assist the Committee in coming to a decision on which drug/medicine was the more appropriate (Jordan Rational Drug List V1, 2006).

The WHO recommend that, It is important to have preferential factors for evaluating therapeutically equivalent drugs: when two or more drugs are therapeutically equivalent, preference should be given to the drug that is thoroughly investigated, and therefore, best understood with respect to these properties and limitations, and as a result, it was advisable through the Jordanian selection committee to choose the drug that is clinically appropriate for more than one disease, this will contribute in further cost reduction, it is always wise to choose a medicine that has favourable pharmacokinetic properties and an easily produced dosage form. It is proposed by the WHO and the Jordanian Selection Committee agrees that such practice will improve compliance, and minimize risk (Jordan Rational Drug List V1, 2006).

Another important measure in choosing a medicine to be used on a countries list is the chemical/ biochemical stability to a range of climatic conditions. Taking note of this aspect is likely to improve risk minimisation of short and long term stability of certain medicines towards weather conditions and if the medicine requires special storage and handling facilities, this could result in an added cost if special management was required and in these cases the committee may give preference to medicines with a reliable local manufacturing and storage facilities (Jordan Rational Drug List V1, 2006).

Choosing a particular medicine formulation is important and the Jordanian MSC has addressed this aspect in their recommendations. In this respect the Jordanian MSC following the WHO Essential Medicines selection guidelines has regularly recommend the use of single compound medicines, but in some cases fixed-ratio combinations are proposed where the clinical value of simultaneous use of more than one drug is documented, and therefore the therapeutic benefit of the combination can be greater than the sum of each of the individual components. In many cases the cost of the combination product can be less than or equal to the total cost of the individual products. In addition,

it has been shown that combinations can improve compliance, and if this fixed-ratio combination is available in sufficient quantities to meet the needs of the majority of the population and the quantities can be maintained through the purchasing process. (Jordan Rational Drug List V1, 2006).

The Jordanian MSC also recommends Periodic Review of the Essential Medicine List: in this case, annually or whenever necessary to incorporate significant new therapeutic advances and information. The committee generally recommends that new drugs should be introduced only if they offer distinct advantages over previously selected drugs, and medicines can be deleted from the List, on the basis of the presence of new information, or where drugs already on the list are found to no longer possess a favourable benefit/risk ratio, typically this effects drugs with a higher benefit/risk ratio. One other aspect which is proposed in the guidelines of the Jordanian MSC is the recommendation to use International non-proprietary names: generic names where appropriate in naming drugs/medicines.

The Jordanian MSC made The Jordanian Food and Drug Administration (JFDA) registration a major requirement for any medicines to be included in the Essential Medicine List (Jordan Rational Drug List V1, 2006).

Overall the medicine selection process adopted by the Jordanian MSC is similar process to the WHO recommendations, one area of the WHO guidelines which has been considered in Jordan is the philosophy as set out in a section of the publication by the WHO 2003, *"How to develop and implement a national drug policy"* (WHO, 2003), which states that the selection process is a two-step process. The first step is the market approval of the drug, which is granted after the medicine, undergoes rigorous testing and quality testing, this step is logical and pre-requirement of any medicines before being marketed in any country. The second step is the comparison of the drug with other similar drugs and compares its cost alongside its benefit.

The Jordanian MSC has generally focused on medicine quality, a cost-effectiveness criteria, medicines pharmacokinetic properties, the availability of storage facilities that ensure the maintenance of medicine quality. All of these

factors should be important when developing an EML in Kuwait and are similar in both the WHO Expert committee recommendations and the Jordanian MSC

The Ministry of Health regulators in many developed countries and the WHO Expert Committee also suggests that a fixed-ratio drug is better choice rather than a combination, but it is suggested that combination products could be chosen if there is a proven their advantage, and this again is an approach followed by the Jordanian MSC. Generally, the countries which have a successful medicines supply chain across the world and the WHO Expert Committee suggest a country should operate on the basis that the selection of drugs/ medicines should be evidence based on post market evidence of efficacy rather than just a method of selection based only on science based experiments. However, in a developing country it is not possible to carry out suitable robust clinical studies and therefore the WHO Committee advised one answer to address the suitability of regularly used medicines is to follow texts such as the Essential Medicine library to gain quality information to the limited list. In addition, the WHO and other major Medicines Regulatory Groups encouraged the use of the large Pharmacovigilance Data Programmes and for countries to launch their own pharmacovigilance programmes in countries to monitor medicines safety and to 'feed' this information into the Pharmacovigilance Databases. However, when examining the use of this aspect in Jordan, it is clear that the use of Pharmacovigilance programmes has still to be introduced in that country (Jordan MOH, 2006).

Overall, the proposed WHO selection criterion has evolved through the last 20 years. One such movement is towards the development of small differences between countries who have initially introduced a list similar to that proposed by the WHO, but have adjusted their list of medicines with time and as a result the criterion used and the medicines considered have become more suited to countries' own health profiles and situation.

2.2.9 Essential Medicine List General Outline

An Essential Medicine List as proposed by the WHO is divided into sections; the first section proposed could include the Master EML, the Core Medicines, and Complementary Medicines.

The WHO describes the *Core List* as being the list of minimum medicine needs for a basic healthcare system, and the list includes the most efficacious, safe and cost-effective medicines for priority conditions (WHO Model EM, 2013).

The *Complementary List* is described by the WHO as being essential medicines for priority diseases, for which specialised diagnostic or monitoring facilities and/or specialist medical care and/or specialist training are needed. In case of doubt medicines may also be listed as complementary on the basis of consistent higher costs or less attractive cost-effectiveness in a variety of settings (WHO Model EM, 2013).

The actual Essential Medicine List document presented in a similar way in most countries, few variances are presented and the variances are country-specific and relate to each country's health profile, mainly each EML document will include a front page, Explanatory Notes, explaining symbols included in the list, List of Essential Medicines, medicines divided in accordance with their therapeutic effects, Medicines with special considerations, such as age or weight restrictions, Explanation of dosage forms and an Index.

Basically, this type of sectioning and styling of the EML document is a common practice in any documents; it's a way of making it user friendly and understandable by the readers.

2.2.10 Summary

The Concept of EML is based on having a limited number of carefully selected Essential Medicines, the concept focuses on improving the health services from various angles, it provides better drug usage and control, and if utilised efficiently it will lead to cost reduction.

The WHO define EML as '*those that satisfies the priority health care needs of the population"* (WHO. 2016) therefore, disease burdens need to be identified clearly, the quality of medicines needs to be rigorously assured, otherwise the EML fails to accomplish its objectives and it would be a useless attempt to enhance the health of the population and a big waste of funds, staff time and efforts.

The following step is the actual content of the List, it's important to follow a very transparent approach to medicine selection and the medicines on the list should to comply with the local Standard Treatment Guidelines, otherwise it might be useless and doesn't really fit with the local health needs.

The medicine selections would be more efficient if it considered the safety of the medicines, the efficacy and evidently the cost-effectiveness. At this point, an important consideration might be useful to fully acknowledge that just because a medicine is cheap doesn't necessary make it suitable for a certain setting; it might be wiser to consider other factors, such as the total cost of the treatment duration, the level of patient compliances factor towards less frequent dosing medicines, and the total cost of a medicine if it requires a special healthcare facility or expert to administer it.

Once the list is designed and published, it doesn't get operational spontaneously, appropriate regulations might help in enforcing adherence; procurement should be based on the EML. Continuity and sustainability very important factors and would be advantageous to arrange regular revisions and updates at suitable intervals, the WHO suggest revision every two years, but that is just a suggestion and each country can use own methods and figure out what is the most suitable interval for updates, providing it doesn't takes too long.

The list lasted close to 40 years, it's been adopted by a large number of countries with various levels of income. Many international none-profitable organisations base their selection of medicines, for donations and in case of disasters, on the WHO Model list of Essential medicines, such organisations are; World Bank, GFATM, Unicef, and UNFPA. All the previous demonstrate a level of success to the EML, but being selected by international organisation might be due to the fact that this list is the only list of medicines that is available and it would be easier to adopt the WHO Model List of Essential Medicines rather than making a huge efforts and come up with their own List of medicines.

Once a healthcare setting adopts the list in its typical form, and adapts it to the local health needs and practice transparency in the selection of medicines, the EML might have a positive impact on the quality of services, budget and fund control.

The Medicines Sans Frontiers, stated that the '*the first List of Essential medicines was a major breakthrough in the history of medicines, pharmacy and public health'*. The reason behind this statement were unclear and no evidence to support it, but the EML as a general concept could be beneficial and might help in providing fund control and improve quality of Healthcare, and if that happened it might be considered as a breakthrough in the history of medicines.

2.3.0 Relationship with the proposed WHO Outline and the Problems & Context for Kuwait:

The Ministry of Health (MOH) at the State of Kuwait has a problem of escalating costs in its health budget and should deal with problems associated with re-organising the issues relating to the budget The Medicine budget represents a major part of the MOH general budget (Kuwait MOH Budget, 2013). The medicine List in Kuwait public sector is massive and includes over 4500 medicines (Kuwait CMS. 2015), such intensive list makes it difficult for the healthcare professionals to prescribe efficiently and might make it challenging to correctly follow up the patients. As a result, the general health will suffer and the budget will keep increasing.

Attempts were made to control the situation, several reregulation and restructuring of the pharmaceutical sector were attempted (Kuwait FDFA, 2013), some were moderately successful and many failed to proceed and produce its objective, despite all the attempts the budget is still inflating and serious measures are required. The concept of Essential Medicines is none-existing, and because of this there are no focus on a group of medicines during procurement, and that is another issue that requires deliberation.

Consequently, the focus of this research project is to measure the suitability of the concept of EML to Kuwait; the research will attempt to examine the barriers to developing and implementing an evidence-based EML. In this respect the research study intends to make recommendations for the implementation of such a policy in Kuwait.

2.4.0 The State of Kuwait Health Profile and Health Economic Indicators

Kuwait occupies the north-western corner of the Persian Gulf. It has a boundary in the East with the Gulf and in the southwest by Saudi Arabia and in the north and the east Republic of Iraq, with a total land area of 17818 square kilometres. The climate is intensely hot in summer with short cool winters (WHO EMRO, 2006).

2.4.1 Demographic Profile

In mid-year of 2010, the population of Kuwait reached 3.6 million however, of these only 31.8% was Kuwaiti (Kuwait Health, 2010).

The population of Kuwait is distributed into 6 governorates. The highest density is seen in Farwaniya governorate with a population close to a million, but they are mostly non-Kuwaitis. On the other hand Kuwaitis presented in the highest concentration in Al-Ahmadi Governorate (Kuwait Health, 2010).

2.4.2 Kuwait Economy

Kuwait has a geographically small but wealthy, relatively open economy with crude oil reserves of about 102 billion barrels – about 7% of world reserves. Petroleum accounts for nearly half of GDP, 95% of export revenues and 95% of government income (CIA, 2013), these figures indicates that Kuwait solely counts on the Oil revenue as a source of income and such situation could be risky, it's always important to diversify the economy, this is apparent now with the current crisis of Oil prices dropping, but Kuwait acknowledges its dependence over oil as its main income, for this reason they have tried to move towards other resources and explore more investment options. As a result, in 2010, Kuwait agreed on a 5 year plan costing 130 billion dollars to diversify the economy away from oil (CIA, 2013).

What Kuwait did following the Invasion of Kuwait by Iraq, is to starts international investments opportunities to help in the future, if similar situation might occur, Kuwait currently owns several important investments worldwide, and with the current Oil crises these investments has been helping but the

recession is near and this is evident by the current rise in the domestic vehicle petrol rise in Kuwait, the prices of petrol at the local market has risen by almost 80%, this caused a lot of anger and dispute in the local community and still until this current time being debated officially to try to come up with a solution (Zainab Calcuttawala. 2016).

What comes in mind at this point that the drop in oil prices internationally has its effects on Kuwait financial capabilities, the results is a form of a decline in Kuwait economy, this decline not only affected the local petrol cost but it is affecting several aspects of Kuwait life and particularly the health services, this is seen in the form of the department of treatment abroad at Kuwait MOH, this department used to send patients that requires treatment not available in Kuwait to renowned health treatment centres abroad, due to the current economic decline in Kuwait, this department had made a very strict rules to reduce the number of patients, looking at this approach it can be viewed in a positive manor, this used to be considered as a source of draining to health recourses, its believed that by applying restrictions this can save on budget, and only patients that requires serious treatment that is not available in Kuwait can utilise this service, from this information it can be established that Kuwait is in search of means to reduces expenses, at this stage of financial restrictions, it might be useful to look at other countries that is suffering from similar financial crisis and adopted a suitable measures used by them to control the financial worries.

2.4.3 Kuwait Healthcare Services

Kuwait healthcare services technologies are comparative to average European standards (EMBRO, 2006). This has resulted from the excellent government spending on healthcare developments since the independence in 1961. But there is no physical evidence of the actual efficient utilisation of the medical technologies and no data published to support the level of health among Kuwait population.

The history of healthcare services is reported to date back as early as 1910 in a form of American missionaries, establishing what is known as the American Hospital. But it is also reported that the healthcare services are even

older than this, and actually started in the beginning of the twentieth century, when doctors from the Dutch Reformed Church were invited by the late Amir of Kuwait to establish a clinic (WHO, EMBRO, 2006). The establishment of the Ministry of Health then followed in 1936.

The year 1949 marked the start of the current healthcare system, by the launching of the first hospital in Kuwait. The Amiri Hospital was then followed by the Kuwait Oil Company Hospital in 1950. This period relates to the start of a full health service which has been free of charge until current date. This comprehensive free service ranked the health service in Kuwait as third in terms of budget after public works and education (WHO. 2006).

The Health Service in Kuwait is divided into two main sectors, the public sector and the private sector, both overseen by regulations and monitoring from the Kuwait Ministry of Health. The following diagram represents the distribution of healthcare facilities.

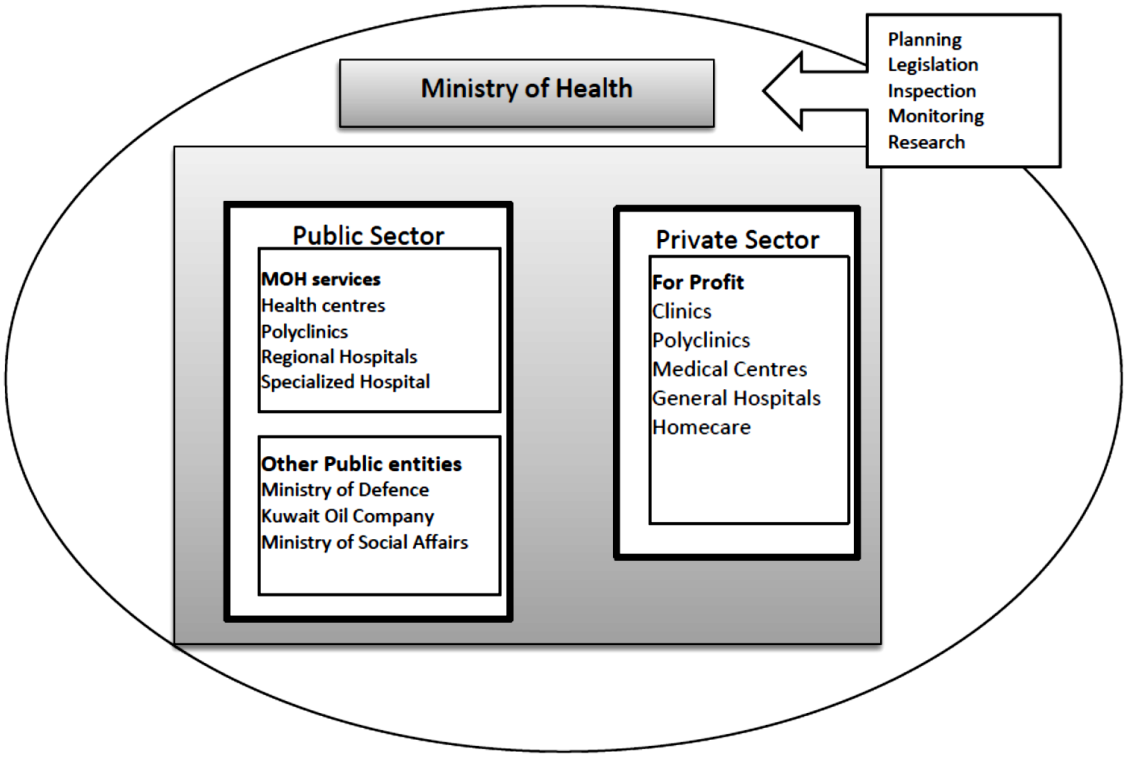


Figure 2.3: Kuwait Health Care structure
Source: made by author based on information from Kuwait MOH public relation department

According to Regional Health Systems Observatory (EMRO), 80% of the health service is provided by the public service, and includes the KOC Hospital and Ministry of Defence Hospital. The services are provided at three levels; the primary healthcare is presented as general and specialised poly-clinics, followed by secondary healthcare services in the form of general hospitals, then the tertiary healthcare facility in the form of highly specialised hospitals.

2.4.4 Challenges, Issues and Constraints

Kuwait's health system is praiseworthy in relation to the availabilities of modern and up-to-date medical technologies to help in diseases diagnosis and treatments, but it still faces challenges. It is suggested that these challenges could lead to serious concerns if it is not controlled appropriately in the not too distant future.

One of the main issues of concern is public expectations; for instance, the educated patient expects a very high quality service, meaning that when some new technologies is available somewhere in the world, patients expect it to be available in Kuwait and they require access to it. Another expectation by patients is medicines availabilities, similarly to any new technologies, patients requires all new medicines to be accessible and available the minute this new medicine hit the market, without any regards to its post market evidence of its efficiency or cost-effectiveness value. Such requirement is far from being realistic; no healthcare system can provide unlimited medical technologies and new medicines to its recipients at all times with no solid and scientific proof of its benefits. Another healthcare recipients concern is related to the fact that patients have low confidence in the efficacy of generic medicines. Some patients look at generics as being second-class medicines, and some other patients term generics as not original medicines. This situation is important and requires measures to resolve it, as the generic medicines can be considered as a useful method to control the healthcare budget and provide a good health outcome. But patients view on generics requires a good public education campaign to explain the concept of generic medicines and its value and to

explain the difference between generic medicines and counterfeit medicines, these two types are seen by patients as being one.

The second challenge is the demographics, as it is predicted that number of people over the age of 60 will increase considerably in the next decade, as the life expectancy age is increasing, which is linked into better healthcare and appropriate medication. This in turn is leading to patients on medication for serious and chronic illnesses such as, cancer, coronary heart diseases and mental disorders for a number of years. Another major issue with the health system is the tendency towards curative services rather than preventive services; and it is predicted worldwide that this is likely to cause a large increase in cost in the future. It is also proposed by health officials across countries that the best approach to improve a health service is to attempt to reduce the prevalence of disease through appropriate public education and it is expected that Kuwait should adopt this stance.

2.4.5 Pharmaceuticals

The 1987 Ministry Decree no 1987/212 announced the official establishment of the Pharmaceutical Services in the State of Kuwait.
At that time the percentage of purchase from the local and regional (gulf area) companies against the total purchase costs of medicines was 9.3%. Whereas the percentage of purchase from foreign companies to the total purchase price of medicine was 90.7% (Kuwait MOH web).

Policies were introduced which led to an alliance with the Central Medical Stores and aimed to resolve any issues and help to improve patient care.

During this time the pharmaceutical services realized the importance of maintaining highly qualified employees within the Department as a result, it now provides continuous training to enhance the performance of all staff.

2.4.6 Central Medical Stores (CMS)

This Store ensures the supply of all health-related requirements, in accordance with the laws set out by the State of Kuwait. The CMS was officially launched in 1984 on a plot of land of area of 75500 square meters with storage capacity of 44000 cubic meters. The area is divided into 60000 extendable storage locations, which are of different types catering for different storage requirements. In these units, the storage temperatures can vary from 15 degrees below zero up to 21 degrees above zero, such massive store indicates that the medicines requirements in Kuwait are high, and the number of medicines is very high, therefore it requires very big storage facilities to cover it. This another form of budget strain, if the medicines list is minimized and the number of medicines is reduced to the medicines related to local health conditions, there will not be a massive need for a big storage facilities and large workforce to manage it.

As a unit, the CMS caters for all needs of the MOH. In addition, it also caters for the needs of other specific healthcare centres including the Kuwait Oil company hospital, Ministry of Defence hospital, National Guard hospital, and Ministry of Social Affairs. The CMS operates as four divisions; the first one is Medicine Control division, the Medical Supplies Control division, Laboratory Materials Control division and Import & Export Affairs control.

2.4.7 International Standardisation

The MOH regulations for all aspects of Healthcare have been continuously reviewed and altered, however some of the regulations are dated and relate back to the early days of establishing the government health sectors, and other regulations generally result from the continuous changes in the MOH. Some of which have come from, minor political instability resulting in multiple changes from within the Ministry of Health (Kuwait MOH, 2010). The changes mainly relate to the frequent changes in the Minister of Health, and such frequent change could carry with it a sort of instabilities in the decision-making process and might halt any new innovations. In reality, the MOH attempts to innovates start on a strong note, then pauses once a new Minister of Health get

appointed, some of the innovative ideas get redirected in a different course other times they stop completely and the funds and efforts that have been employed to support the innovative process get wasted, this is another form of budget strain and wastage.

For these reasons the MOH decided in 2010, to follow the international guideline, and employ a team of experts who would look at standardising of the healthcare services. As part of this development in August 2010, the Kuwait MOH commissioned 'Accreditation Canada' a private consultancy company to provide technical advice, with the aim of proposing a model for health services accreditation activities. This was another innovative step that been suggested by a higher authority but unfortunately the process came to stop for two years, and the reason was the same as mentioned earlier, is because of the ministerial changes and the new Minister did not want to follow the footsteps of the previous Minister. In 2013 the Canadian Standardisation Team became active again, and that's happened because the removed Minister came back again to authorities and relaunched his previous idea.

However, after I had a look at the work of the accreditation programme, it's been clearly noted that the pharmaceutical services were not a priority and little attention were given to the out-dated pharmaceutical regulations. The Canadian Team spent more time in other healthcare departments and spent very little time at any given Pharmacy at Kuwait MOH, and looking at the Canadian Team Mission Statement, the clinical services that has been supported by them doesn't include any pharmaceutical services, which could explain the little time the team spend in any of the MOH pharmacies.

The main reason the senior healthcare officials sought out the help of the Canadian team was to try to practice some type of control over the health services, to try to strengthen some parts of healthcare services and try to come up with solutions as to why the MOH budget inflation is high. With that in mind and the fact that the medicine budget is a big part of the MOH budget, it would have been wiser to try to perform a type of updating to the pharmaceutical and medicines services.

Unfortunately, until the end of this research the Canadian Team has not fully reviewed the system and the intended work is not fully accomplished, what has been attempted by the Canadian team was to pass out several posters to each Department at the MOH with the suggested Standard Operation Procedures related to that particular Department, it's a good step and might help in time managements but might not have a big impact on the budget inflation and did not organise any Department in relation to prescribing, patients care, counselling, quality of service, referral processes and there was no clear innovative policies in place.

Overall, this attempt to reorganise the healthcare services in Kuwait might have missed its target, and the MOH budget inflation still a problem, and the medicines budget still account of a large portion of the MOH budget and no practical action been adopted to control this case.

It would be wiser if the MOH senior officials target the source of inflation and try to come up with solutions to this particular problem, having a massive list of medicines that keeps expanding with little thought to medicine cost could make the budget increases even further, and such a massive list of medicines that is currently present at Kuwait MOH could be difficult to handle, manage and store, and that's again another fund drainage.

It might be useful at this point to discuss the health economics and try to understand the health budget and what could be the source of drainage and try to come up with suggestions on how to resolve the situation.

2.5.0 GCC Countries and the State of Kuwait Health Profile and Health Economics

The Gulf Cooperation Council (GCC) – includes the Kingdom of Bahrain, Kuwait, the Sultanate of Oman, Qatar, the Kingdom of Saudi Arabia (KSA) and the United Arab Emirates – and was founded in Abu Dhabi in 1981(Deutsch Federal Foreign Office, 2012). In addition, Jordan and Morocco were recently invited to join the Council (AL Sharif, Asma, 2011). The GCC seeks to foster peace and security in the region, as well as economic integration among member states. It also aims to unify regulation among member countries, keep up with the advances in Technology and Science, form joint military forces by forming the Peninsula Shield Forces and to strengthen bonds among all members' citizens (A B Sturm, et al, June 2005) (Abed, George T. 2003).

2.5.1 Geographical Location of GCC:

The GCC states are located in the Arabian Peninsula Southwest of Asia between the latitudes of 15 and 35 north of Equator and longitudes of 35 and 60 east of Greenwich, bordered by Iraq and Jordan in the North, Republic of Yemen and the Arabian Sea in the South, Arabian Gulf in the East, and Red Sea in the West (GCC Facts sheet, 2010).

2.5.2 GCC Population

The surface area of the GCC countries is distributed unequally and as a result the population is variable, a large surface area country such as the Kingdom of Saudi Arabia, has a big population of 25.3 Million with a large number of rural Areas, where a small country like the Kingdom of Bahrain has a population of one million only and everything is at close proximity. Such variances could result in different health related issues, for example having a number of rural cities will give rise to an efficient transport system for medicines and health related services, such situation might have an effect on the health budget, the variation in the population will evidently requires suitable allocated budget, a large population could require a bigger budget to cover its health needs.

The following table adapted from the GCC library represents the population distribution among GCC countries in (2007/09).

Table 2.5: GCC countries population variation from 2007-2009				
Country	**2009** (in Million)	**2008** (in Million)	**2007** (in Million)	**% change in 3 years**
U.A.E	4,8	4,8	4,5	6.2
Bahrain	1,1	1,1	1,0	6.5
K.S.A	25,4	24,8	24,2	4.7
Oman	3,2	2,9	2,7	15.7
Qatar	1,6	1,4	1,2	25
Kuwait	2,6	2,5	2,4	7.6
Total	38,7	37,5	36,0	6.8
Source from GCC; a Statistical Glance; Vol II, Information Centre- Statistical Dept., Dec 2010.				

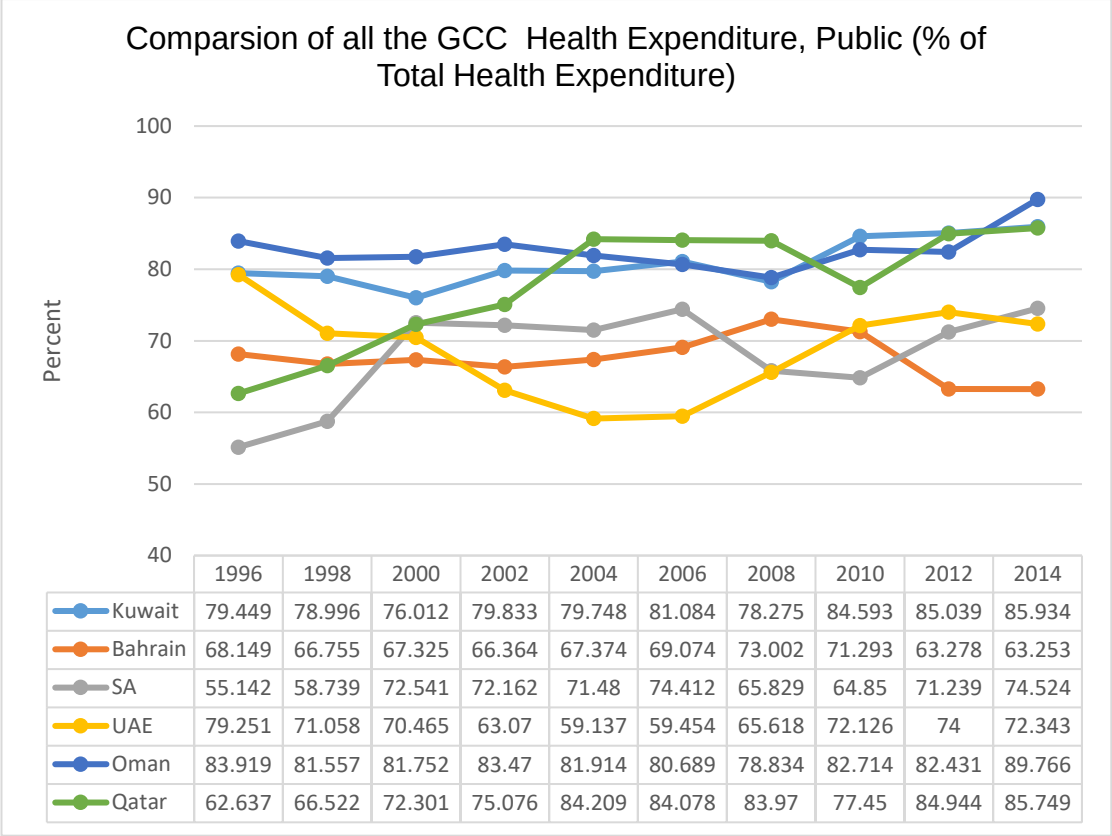
The table above demonstrate an increase in the GCC countries population, there is a big increase in Oman and Qatar, such changes could have some sort of an impact on the health services, this increase in the population in Qatar can be explained due to the rapid economic growth Qatar recently faced. This has happened due to the discovery of Natural Gas, that required more of a workforce to build Qatar energy infrastructure, therefore, there is an increase in the population, mainly western immigration (Leah Hyslop. 2010). Similarly in Oman, expatriates represents 45% of the population, but they are mainly Indian and Bangladesh (Gulf News. 2016), who were all needed to build the country's infrastructure, this situation of a rapid increase and sudden increase in the population might have an impact on the health services, and it will require more medicines access for the larger population. Since the increase is rapid and unplanned it might cause a type of a problem in healthcare and medicines. Another important health constrain that might appear due to this sudden migration, is the diversity of the population ethnicities that requires different method of health adaptation, such a problem is apparent in the Kuwait population, where 69% of the population is expatriate and mainly Indian and Bangladeshi (Kuwait Public Authority for Civil Information. 2014). In a situation like this the healthcare might need to cover a wider ethnicities and diseases profile and health requirements might differ, not accounting for the population diversity might lead to inefficient healthcare, and

might consequently cause the population to suffer and loose its confidence in the health system.

A more recent increase in the population of Bahrain also been registered, and this has been the case because Bahrain has allowed the Syrian refugees to remain in Bahrain until the resolution of the crisis in Syria (Arthur Miller. 2016), such approach might bring with it new health-related conditions. For instance, some refugees might require psychological counselling to help them overcome what they have gone through and help them to accept the new way of living. Some have war related injuries that requires serious intervention and might need invasive medical procedures to help them recover, but all this requires further expenditure and will cause further health budget inflation.

Overall, the GCC states share a similar geographical structure; furthermore, they are similar in the socio-economic environments, parallel encounters, strains and the standard of living are relatively alike, the large percentage of expatriates in the GCC countries can be related mainly to the economic growth that the GCC countries went through, since the discovery of the oil and gas. This discovery left the GCC with the requirement of a large work force to deal with the recently discovered wealth, and because such fortune brought with it an attractive level of living and excellent financial rewards, the GCC countries became more desirable for the foreign workforce, and such a situation could have an impact on the health requirements and makes them unpredictable and could eventually inflate the health budget.

The following figure represents a comparison between all the GCC Health Expenditure, Public (% of Total Health Expenditure), the percentage has been measured with three decimal points due to the proximity of the values. It clear that the GCC countries share similar spending trends in healthcare, and the healthcare is a priority in the overall government budget. There is variation in the allocated budget and this is due to the variation of Oil revenue, since all the GCC countries depends on oil production as the main source of income.



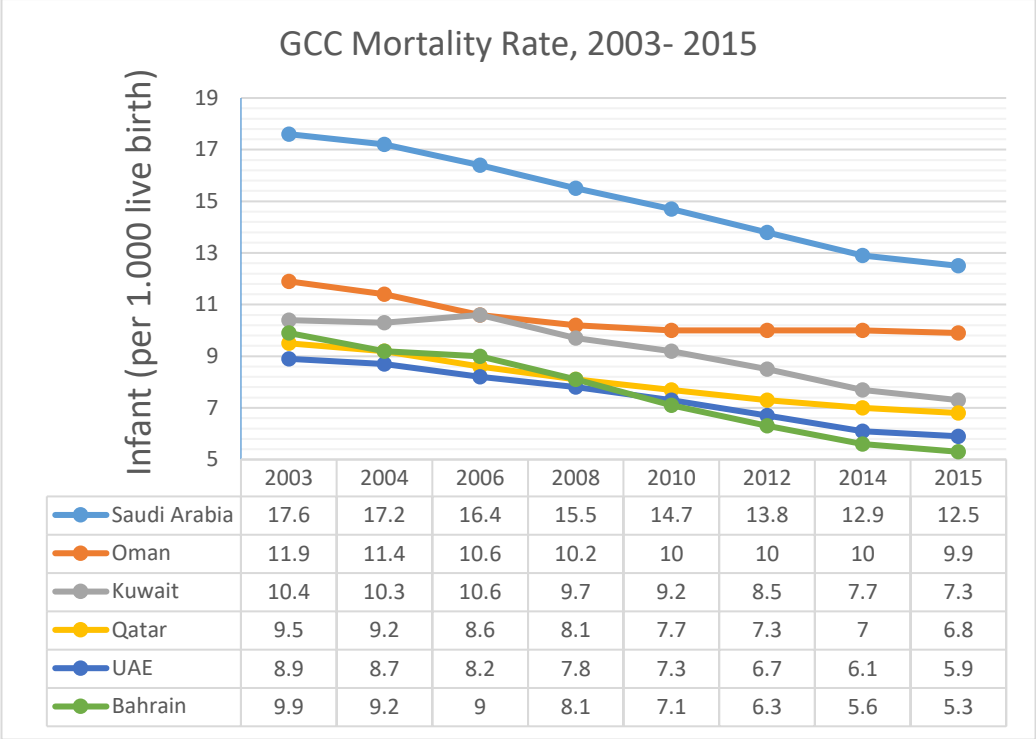
	1996	1998	2000	2002	2004	2006	2008	2010	2012	2014
Kuwait	79.449	78.996	76.012	79.833	79.748	81.084	78.275	84.593	85.039	85.934
Bahrain	68.149	66.755	67.325	66.364	67.374	69.074	73.002	71.293	63.278	63.253
SA	55.142	58.739	72.541	72.162	71.48	74.412	65.829	64.85	71.239	74.524
UAE	79.251	71.058	70.465	63.07	59.137	59.454	65.618	72.126	74	72.343
Oman	83.919	81.557	81.752	83.47	81.914	80.689	78.834	82.714	82.431	89.766
Qatar	62.637	66.522	72.301	75.076	84.209	84.078	83.97	77.45	84.944	85.749

Figure 2.4: Comparison of the GCC health Expenditure, created by the author, sourced from the World Bank stat.

Another measure used internationally to estimate the health of any given population is Morbidity and Mortality rate**.**

Infant mortality rate is the number of infants dying before reaching one year of age, per 1,000 live births in a given year. Reductions in infant mortality are possible in any stage of a country's development (Bishai, 2007). Rate reductions are evidence that a country is advancing in human knowledge, social institutions and physical capital. Governments can reduce the mortality rates by addressing the combined need for education (such as universal primary education), nutrition, and access to basic maternal and infant health services.

The following figure represent the Infant mortality rate in the GCC since the year 200 until 2014.



	2003	2004	2006	2008	2010	2012	2014	2015
Saudi Arabia	17.6	17.2	16.4	15.5	14.7	13.8	12.9	12.5
Oman	11.9	11.4	10.6	10.2	10	10	10	9.9
Kuwait	10.4	10.3	10.6	9.7	9.2	8.5	7.7	7.3
Qatar	9.5	9.2	8.6	8.1	7.7	7.3	7	6.8
UAE	8.9	8.7	8.2	7.8	7.3	6.7	6.1	5.9
Bahrain	9.9	9.2	9	8.1	7.1	6.3	5.6	5.3

Figure 2.5: GCC Mortality Rate, created by the author, sourced from the World Bank.

The overall finding is that the Mortality rate is declining and the GCC countries have similar mortality rate except of Saudi Arabia, which is slightly higher and that could be because Saudi Arabia is a large country and has a large number of rural areas, and comprehensive health services might not be available to all.

In regards to the Morbidity rate at the GCC countries, which can refer to either the incidence rate, or the prevalence of a disease or medical condition. This measure of sickness is contrasted with the mortality rate of a condition, which is the proportion of people dying during a given time interval.

It would be useful to consider the expenditure on medicine in Kuwait , by age and gender, and compare it with the GCC countries but Such data is not available.

As indicated previously Jordan was not one of the original GCC countries, but has recently been invited to join the other countries and brings with it a level of organisation not generally seen in the other countries. Short

descriptive backgrounds to the health position of these GCC countries are given below, starting with Jordan. The reason for choosing Jordan as an example to describe its health system, is because Jordan is the only GCC country with limited financial resources, and for this reason they have adopted many policies to control the inflation of healthcare cost. Furthermore, Jordan shares a number of similarities with Kuwait in terms of health profile and disease burdens, where the three main causes of death in Jordan are Cardiac problems, Road Traffic Accidents and Cancer (WHO. 2014). These health conditions are similar to Kuwait, and by looking closely at the Jordanian experience it might give an indication on how the State of Kuwait might gain an experience and could utilise it to reorganise the healthcare services at the State of Kuwait, or could use the gained experience to predict problems and prearrange a method of overcoming such problems.

2.5.3 Hashemite Kingdom of Jordan

Jordan is a relatively small country with a total area of 89,342 square kilometres and an estimated population of 5.6 million (Department of Statistics. Jordan in Figures, 2006). It is bordered with K.S.A in the north resulting in a similar climate and social behaviours. The countries' economic position is however different than that seen in the other GCC countries, and according to the National Poverty Strategy (2002), in Jordan there are up to one third of Jordanians living below the poverty line (CIA fact-book, 2013). On the other hand, the rest of the GCC countries, do not have any published figures to the percentage of the population living under the poverty line, therefore, the comparison between Jordan and the GCC countries in relation to the level of poverty is not possible. However, such comparison would have been useful to help in understanding the level of healthcare affordability by the whole population at several levels of incomes and out-of-pocket cost.

2.5.3.1 Population of Jordan

The first population survey was in 1961 and the latest survey results indicate that the population in 2010 was close to 6 million. Over the years, the average growth has fluctuated, due to a number of reasons, and in particular because of the many political interruptions. The population growth was highest

between 1979 and 1994 due to influx of immigrants from the West Bank and Gaza, because of conflict in these areas. Also, population growth occurred, following the Gulf Crisis in 1990 when it was estimated up to 300,000 Jordanians returned from the Gulf States and also in 2003 when tens of thousands of Jordanians who lived in Iraq returned to Jordan following the second Gulf war. Added to these numbers, at the same time, a very large number of Iraqi immigrants relocated to Jordan, and in recent years and since the start of the Syrian revolution there is another influx of migration from Syria, with people escaping the war and trying to seek refuge in a safer environment. Such a situation caused huge financial loads, and it required more healthcare to help the refugees get over all war related health conditions.

According to the Jordanian Department of Statistics, this inflow of immigrants and the return of Jordanians to the country resulted in several problems of provision of infrastructure support which included putting a strain on government services, particularly the health services and education. This is however true in any sudden disruption in any given population.

2.5.3.2 Jordan Health Care System Organisation

The Ministry of Health as the major healthcare provider, is responsible for all health matters in the country, and is responsible for health promotion, for monitoring all aspects of health facilities in both the public and private sector and providing health education programmes and training. In addition, the Jordanian Food and Drug Administration are in charge of quality control for locally manufactured and imported medicine, medical supplies, drug registration, licensing and pricing. The MOH also introduced a programme known as the Civil Insurance Programme (CIP), for the Public Sector (WHO, 2013).

To clarify the position further, the WHO has published the following table in 2013 in its periodical, Country Cooperation Strategy for WHO and Jordan, 2008-2013, which summarises the different types of healthcare sectors available in Jordan, and who is responsible for funding the sector.

2.5.3.3 Jordan Healthcare Finances

The WHO has also stated that Jordan's total expenditure on health is among the highest in the region, at 9.8% of GDP, which could be partly explained by the constant changes in the population and the refugee crisis that requires serious funds to resolve any war related health conditions.

However, the government share of 51% of the total health expenditure, has since been reduced by 10% between 1998 - 2005 (Jordan MOH, 2006), the figures suggest that there has been a growth in the private sector by 59% (Jordan MOH, 2006). This could be explained in two ways, the first thing might be that patients have more confidence in the private sector rather than the government sector, and it is suggested that this situation requires exploration and evaluation to reach the reason behind such approach. The second explanation could be because the public sector is not efficient enough and the healthcare services is not up to speed with the modern advances in the medical technologies, another point which needs to be considered is the cost of pharmaceuticals in the Jordan public sector account for one third of the total health budget, which places Jordan among the highest spenders on medicines (WHO, 2013).

Jordan has similarities to the state of Kuwait in terms of the availabilities and access to health-related data, but unfortunately there is a lack of research within health authorities in Jordan; and although there are many ideas on what to research, but the main problem is lack of information (Ibrahim Al-Abbadi, 2007).

The different sectors of healthcare and its eligible beneficiaries are demonstrated in Table 2.6.

Table 2.6: Providers of Health care and eligible/beneficiaries in Jordan			
Sector	**Authority**	**Eligible/Beneficiary**	
Public	MOH	Civil Insurance	
		Any citizen, resident or visitor	
		Other insurance – MOU	
	Royal Medical Services (RMS)	Military insurance	
		Private customers (including visitors)	
		Other insurance - MOU	
	University hospitals and specialized centres	Jordan University Hospital	Own constituency
		King Abdullah I Hospital (JUST)	Other insurance
		King Hussein Cancer Centre	Private customers
Private	Clinic	Private insurance	
	Hospital	Private customers	
	Treatment abroad	Visitors, other insurance	
International	UNRWA	Registered Palestinian refugees	
Non-governmental organizations	National	Red Crescent Society	
	International	Clinics and hospitals	
Source: Country Cooperation Strategy for WHO and Jordan			

The health sectors in Jordan is slightly different from that available in Kuwait, but the similarities is in the fact that Jordan and Kuwait both have Public and Private sectors, but Jordan receives further aid from international organizations and non-governmental organizations, this is the case in Jordan because the Palestinians and the more recent Syrians refugees crises, and because of the fact that one third of the Jordanian population lives below the poverty line. Such a scenario is not present in Kuwait, the reason could be because Kuwait doesn't receive any donations but on the contrary Kuwait is ranked the highest donators in the world.

2.5.3.4 Pharmaceuticals

25% of medicine needs in Jordan are manufactured in the country, the rest are imported. Although local production of medicines in Jordan is not enough to cover the country's needs, the Jordanian pharmaceutical industries manages to sell medicines to other surrounding countries (Jordan Ministry of Finance, 2004). One operational matter which has been organised in Jordan is the National Medicine Policy and part of the policy is the Essential Medicine

List, which was established in collaboration with the WHO and the World Bank. By introducing this Policy, Jordan MOH believes that it has been possible to move towards better control of the inflation related to the cost medicine.

In Kuwait, there is one medicines and pharmaceutical factory, called the Kuwait Saudi Pharmaceutical Industries Company, KSC. It was established as a Kuwaiti company in the early eighties then after the invasion of Iraq to Kuwait the company was relaunched in co-operation with Saudi Arabia, the factory manufactures 86 generic types of medicines, but this covers a very small percentage of the medicines requirements at the state of Kuwait, Kuwait depends mainly on import for its medicines requirements and this situation is similar to Jordan with one difference, is the fact that Jordan makes 25% of its medicines needs.

In additions to the discussions above the second country to be discussed is the Kingdom of Bahrain, because it's the one of the two GCC with an operational EML, and Bahrain health profile is similar to Kuwait.

2.5.4.0 The Kingdom of Bahrain

Bahrain is officially the Kingdom of Bahrain and is a small island country situated near the western shores of the Arabian Gulf. It is an archipelago of 33 islands, the largest being Bahrain Island, at 55km long by 18km wide.

2.5.4.1 Population

In 2013 the population was suggested by the World Bank to be 1.3 million as compared to 561,872 in 1994 (Health statistics, Ministry of Health 2003–2004).

The following table, was adopted from the Bahrain Health Statistics, (MOH 2003-04), and appears to best describe the population distribution in Bahrain. The table again represents a high percentage of non-Bahrainis and this can again relate to migration from the western world and from Indian for better pay, and the Syrian refugees escaping war.

Table 2.7: Demographic and socioeconomic indicators (2004)	
Total population	**707 106**
Bahraini (%)	62
Non-Bahraini (%)	38
Population below 15 years (%)	24.5
Population 15–64 years (%)	73.3
Population 65+ years (%)	2.2
GDP per capital (US$) (%)	15 572
Unemployment 15+ years (%)	5.5 (2001)
Source: Health statistics, Ministry of Health 2003–2004 Country Cooperation Strategy for WHO and Bahrain 2005–2010	

2.5.4.2 Healthcare System

In 1903 the first hospital was opened by the American Mission, with a bed capacity of 21. Following this another Victorian Memorial hospital opened with a 12-bed capacity. In 1936 a small hospital was established for the Bahrain Police Forces.

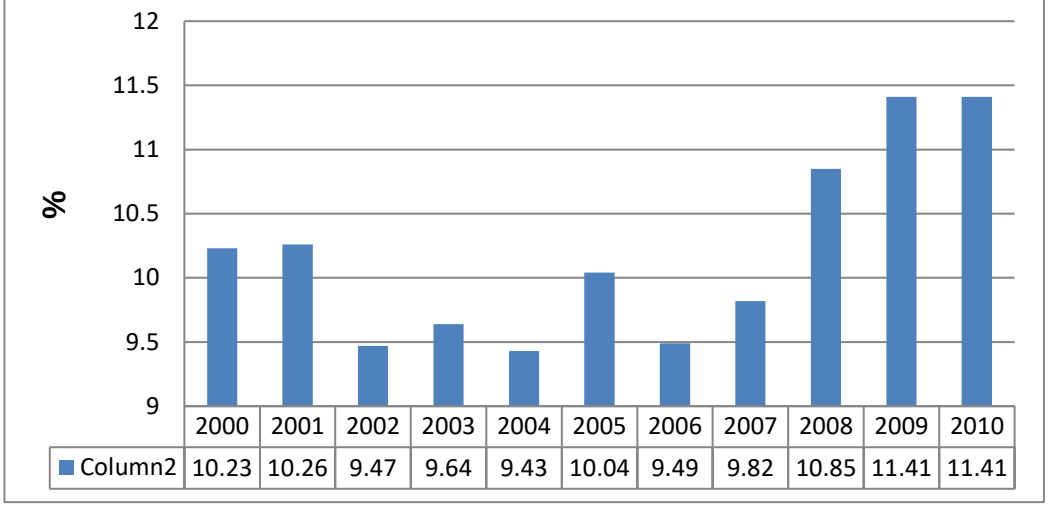
As the population grew there was a need for another well-equipped hospital, and in 1957 the Salmaniya Hospital was constructed.

This healthcare system is very similar to Kuwait, and the method of funding is closely related to Kuwait.

2.5.4.3 Bahrain Health System Financing

In 2004 the total healthcare expenditure including the Bahrain Defence Forces, Private Sector and Ministry of Health, was $282 million US dollar (CCS for WHO and Bahrain, 2010). In the following table is the percentage of the total health cost taken from the national budget from 2000 until 2010 (World Bank Report 2012). From these figures, it’s clear that there has been a rise of 1.5% over the 10 year period.

Figure 2.6: Health Expenditure; Public (% of Government Expenditure) in Bahrain
Source: The world Bank 2012



	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Column2	10.23	10.26	9.47	9.64	9.43	10.04	9.49	9.82	10.85	11.41	11.41

Figure 2.6 and the table indicates the rise in Bahrain health expenditure, with an increase by 1.5% over the ten years which is not a great increase and is very predictable due to the general inflation that is taking place worldwide. The EML of Bahrain were first started in 2009, which was an attempt by Bahrain Healthcare services to control future unexpected inflation.

Bahrain, Oman, and Jordan are the only three GCC countries with an operational EML, other GCC countries like the Kingdom of Saudi Arabia, has a form of EML but not operational and not published yet, for the purpose of this research it is important to view their experience with the list and try to identify what point's need to be considered when planning the EML for the State of Kuwait.

From the information mentioned earlier, Kuwait Oman Jordan and Bahrain have frequent population changes, to be more accurate all the GCC countries suffers from a high percentage of immigration, some political others financial. Such diversity on the population could change the health requirements and the results might be a bigger strain on the health budget, not being able to predict the actual health needs of a certain community due to the continuous changes of the community which might cause a failure to the health system in general and might cause an inefficient medicine supply system, all at the end might have a negative effects on the health budget.

However Oman, Jordan and Bahrain have all made several attempts to control these changes, and the approach that been conducted by these three countries to control the situation was to plan a medicine policy that includes an important medicines in relation to the health requirements of these countries diverse population and try to maintain a reasonable level of medicine supply. The three countries adopted the concept of the EML as an attempt to exert a type of control over the medicine budget, unfortunately, there are no hard evidence data to support the success of this application, this is a recurrent situation in the GCC countries in regards to the availabilities of health studies in general and medicine related studies in particular.

At this point the Health System at the State of Kuwait will be discussed; which might help in understanding what are the issues and allocate the drainage of the Kuwait MOH budget.

2.6.0 GCC Health Profile and Health Economic Indicators

2.6.1 GCC Health Economics

In 2012 the GCC produced a collective document, Statistics at Glance (GCC; Statistics at Glance. 2012), mentions in the introduction that healthcare services have evolved tremendously in parallel with the population and life style growth in GCC countries. This is evident in the increased hospital numbers, in the number of doctors working at the healthcare facilities and in the number of patients per doctors, as shown in Table 7, the figures display that every ten years there is a duplication in the number of doctors and as a results the number of patients per doctor has reduced. This development in the services could be beneficial to the patients, and might help in providing better patient care, but again this type of approach might put some type of strain on the health budget, and if such duplication is continuous, the GCC countries might find themselves with a large number in the work force. With such large workforce it might be difficult to have an efficient follow-up to the doctors performance, and there may be no clear indication as to whether the workforce is fulfilling patient needs and is providing the appropriate care required, and with a large workforce the MOH of each GCC country might increase its health budget to cover the cost of doctors.

Table 2.8: Evolution of GCC healthcare (1990/2011)			
	1990	2000	2011
Hospitals	345	475	635
Doctors	23000	50000	100000
Patients per Doctor	937	-	458
Hospital beds	44500	60000	87000
Source: GCC; Statistics at Glance. 2012			

Over the years the representatives of the GCC committee have taken these figures and converted them to the overall costs, and thus a budget figure. However the figures produced have shown that there has been an increase in the budget allocated to the MOH in each of the GCC countries. The following Table 8 represents the GCC financial resources indicators.

Table 2.9: Financial Resources Indicators										
Country	**MOH allocation from Government budget**		**MOH expenditure as % of GDP**		**Government Expenditure as % of total Expenditure on health**		**Annual budget of MOH (per Capital)**		**National expenditure on health (per capital)**	
	%	Year	%	Year	%	Year	$	Year	$	Year
UAE	7.3	08	0.3	08	69.9	07	217	08	1140	07
Bahrain	10.4	09	2.7	09	70.9	09	417.3	08	657.1	08
KSA	6.2	09	-	-	-	-	310	09	-	-
Oman	4.9	09	1.29	08	82.50	07	269	09	373	07
Qatar	5.1	07	9.7	08	70.1	09	2059	09	2935	09
Kuwait	7.6	10	-	-	-	-	801	10	-	-
UAE: The indicators mentioned above are for the whole union Source: Health Indicators for The GCC, 2011. 15th edition. Riyadh. KSA										

From the table above it is clear that the healthcare services are a big part of the GCC countries general budget, the highest found in Bahrain and the lowest in Oman. In Oman and due to the drop in oil prices and the reduction of 33% of Oman annual oil and gas revenue (Oman State Budget, 2016), the government tried to cut expenditure, and part of this plan is a five year plan to privatise several public sectors including healthcare.

Due to the discovery of Oil and Gas in the GCC countries, resulting in a large revenue, the health services in the GCC countries are much better than they were before the Oil and Gas discovery (McKinsey *et al*, 2012), but the demands on healthcare services are escalating due to the population increase and the immigration from various Western and Asian countries to the GCC countries, in addition the general population are not entirely satisfied with the care level provided, as patients expect to have access to all kind of modern clinical technologies, with no regards to its cost and benefit. Another issue that might require careful deliberation, and could be another form of budget inflation is the lack the proper managerial skills at a high level and for a relatively new modern healthcare system it might be worthwhile to get international medical experts input into the newly developed system, but unfortunately the cash

motivations are often not enough, alone, to attract medical specialists, who are increasingly required by the Health Services,

The GCC Health Statistics suggests that chronic diseases are rising, such as diabetes and hypertension and that the healthcare facilities are not fully appropriate to deal with such an increase, this is the case due to the harsh weather conditions that makes it impossible to practice any kind of outdoor physical activities, because of the high rate of smokers and bad food habits, that all requires cures and it is proposed that it would be wiser if the GCC countries moved towards preventive care and patient education to reduces such prevalence's.

Overall over the last 40 years the GCC countries have been faced with main areas of healthcare concerns, which have led to increases in demand on their healthcare services and consequently have led to increased cost. These are population growth, increased life expectancy and health risk factors.

In the first case it is expected that the size of the population of GCC countries is likely to double by the year 2025 (McKinsey *et al*, 2012), one of the main reasons is due to an increase in life expectancy in the GCC region and a reduction in the infant mortality rate. As a result there will be a more aging population that subsequently requires more healthcare support and this has lead to extra cost. It is estimated, from the study conducted by McKinsey et al 2012, that over the next 20 years the treatment demand in the GCC will increase in the region of 240%. In addition the number of hospital beds will probably need to be doubled to deal with the demands, and it is estimated that the healthcare cost is expected to increase by around five times the present levels.

2.6.2 The State of Kuwait Health Budget

In Kuwait the majority of the Public Healthcare expenditure is linked through the Government Departments, and as an example it was 78.1% and 75.1% in 2000 and 2002 respectively. In contrast only a small percentage is related to the supply of Healthcare support through the private sector and

expenditure linked to the government out of pocket accounts (Kuwait Health Sector report, 2012).

When looking at the yearly figures for Kuwait, overall, the Government is estimated to spend a large amount of money on health services in general and a large proportion of it is spent on the supply of medicines. The following Table (obtained from the Kuwait Government Budget Department, at Kuwait MOH) shows a comparison of the total budget of the MOH and the percentage of the cost of medicines from the total.

Table 2.10: MOH budget and Medicine budget 2006 until 2010 in Kuwaiti Dinar

year	MOH Budget (Million)	Medicine Budget Agreed (million)	KMB Changes	Agreed after changes	%
2006/2007	555,0	84	4,2	88,2	16
2007/2008	638,6	89	1,3	90,2	14
2008/2009	1,019,3	121	0	121,3	12
2009/2010	876,8	140	10,1	150,4	17
2010/2011	1,082,0	144,4	14	158,5	15
2011/2012	1,197,2	217	0	217	18

Agreed and changes of Kuwait medicine budget (KMB) in comparison to the total MOH budget (MOH.B)
Source: Kuwait MOH Budget and expenditure department, 2013
1KD = 3.51 US$

From the data in the Table it is clear that the overall budget of the Kuwait MOH has increased considerably in the past 6 years alongside increases in the medicine budget. It is suggested in the Kuwait Ministry of finance reports that this growth requires consideration and deliberation, and it is presently being reviewed (Kuwait Ministry of Finance. 2015).

During the early part of this study in 2013, the Assistant Undersecretary of the Ministry of Health for Planning and Quality Affairs (Dr Waleed Al-Falah), was interviewed by the major Arab Times News Paper and it was mentioned that the MOH budget rose to almost double in the last five years from around KD 620 million in 2007 to KD 1.197 billion in 2013, that is 2.05 Billion to 3.97 billion US Dollar. In the interview, he added that although the figures have increased considerably, it does not seem to be the case that the health

outcomes are reflected in aspects of efficiency and quality of the Country's Health Services. Dr Alfalah added that he believed that '*improving the health services can only be conducted if there is better handling of the economic tools including auditing, financing, and statistics*'. (Arab Times, 2013, p 4). Dr AL-Falah further explained in an interview with myself in February 2014 where the main points of the his statement for the Arab Times Newspaper were discussed, that Kuwait's Health Services and Healthcare Expenditure however requires careful monitoring and deliberations to control the inflation and to assist in this the health indicators need to be examined carefully and attention should be given to each section. Therefore, there is a need to give special attention to the medicine budget and try to investigate areas in which the medicine budget can be controlled. From Dr Alfalah statement to the Newspaper, its evident that the Kuwait government acknowledge the fact that the medicine budget is rather high and might require some type of reorganising, the statement also indicates that a system or a policy that focuses the number of medicines to a list of medicines that is closely related to the general health needs of Kuwait could be adopted and such system might help in practicing a type of control over the budget inflation.

The following chart demonstrate a comparison of the GCC countries Consumer Price Index for Medical Care in 2011, in the chart, Figure 8 Kuwait has the highest CPI for Health Care, meaning that patients in Kuwait pays higher retail prices for medical goods, including medicines than any other GCC countries. This finding insinuates that patients have higher out of pockets expenses than any other GCC country and might indicate that Kuwaiti patients are moving towards the private sector for treatment and healthcare, and such a situation might require further deliberation to come to decision on the reason behind it.

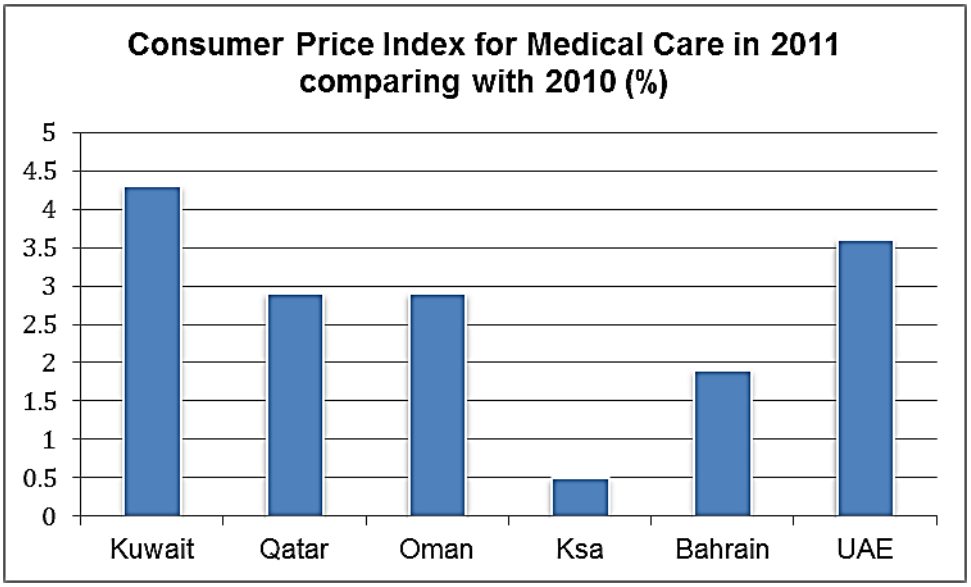


Figure 2.7: sourced from the GCC Library

Chapter 3

Methodology

3.1 Introduction

Research according to Johnson (1994) can be described as being '*A focused and systematic enquiry that goes beyond generally available knowledge to acquire specialised and detailed information, providing a basis for analysis and elucidatory comment on the topic of enquiry*' (white, 2005). Based on this definition or description of the research work, it needs to be concentrated, logical and follow rational steps to be able to answer the research questions.

This chapter describes the methods which were used and the rationale behind choosing each method and how appropriate they are for delivering the required information. This chapter will cover all aspects of the research and data collection process as well as the location of the field work.

It will also define the different types of research philosophy and will demonstrate the best philosophical description for this particular research work.

In the early stage of this research work, it was aimed to investigate and review the current medicine situation in terms of availability, cost and quality at the State of Kuwait MOH healthcare facilities. The methods focus on trying to explore, analyse and discuss the present situation. By doing so it was proposed that the actual concerns could be raised and highlighted. Once this is achieved, it is proposed that some solutions or suggestions for the future of the medicine situation could be generated. Once this was completed, it was proposed to tackle the main area of this study, which is to discuss and suggest whether it would be appropriate to introduce an EML programme into Kuwait. If one was to be introduced, it would be suggested whether it will enhance the general medicine situation of the country and increase its efficiency (Collins & Hussey, 2003).

Later as the research progresses, it moves towards the attempt to extract knowledge and try to identify the processes, which other countries used to develop and established their EML; this part of the research work will attempt to identify the difficulties they faced during and after the implementation of the concept. It was proposed to focus on gathering data from the key actors in the

medicine supply system. This project does purposefully not include healthcare recipients in the data gathering process, because such stakeholders are unlikely to have sufficient knowledge or practical experience of the system to provide any meaningful data.

Later, in the research work, it was intended to make a comparison between previously published and already operational Essential Medicine List's in several countries with various geographical locations and different standards of living.

At the final part of the research there will be a close investigation to the WHO Model List of Essential Medicines, and a close inspection to Kuwait List of Medicines that is available at the Central Medical Stores. Overall it is proposed that by doing this study, it will be possible to formulate the most appropriate recommendations to illustrate how the Essential Medicine List of Kuwait might be presented. Because it aimed in this part of the study to obtain a general understanding of a Kuwait EML, but not the actual list.

3.2 Research Type:

It is proposed that the research can be considered, at the early stage, as being exploratory, because it was found that there are few or no previous studies in this field, which relate specifically to the medicine system in Kuwait. The research methodology was designed from the origin and didn't follow any previous work, simply, because such work does not exist. This finding was established following a very intensive and time consuming literature review that revealed this statement.

3.3 Research Approaches

The research is considered to be a deductive approach, the research aims to deduct the appropriate interpretations to the suitability of the Essential Medicine List to Kuwait. This approach is believed to be the most suitable to this particular study because it should test the major research questions which are, "*What are the contextual factors in Kuwait which would assist or hinder effective implementation of EML?"*

These particular research questions are the reason behind starting the whole research study.

To explain the approach more, we can quote Beiske (2007), by explaining that '*The deductive approach follows the path of logic most closely. The reasoning starts with a theory and leads to a new hypothesis. This hypothesis is put to the test by confronting it with observations that either lead to a confirmation or a rejection of the hypothesis*' (Snieder and Larner, 2009, p.16).

The deductive approach tends to test theories, phenomenon or concepts, and in this type of work, the concept of EML will be tested. The outcome will be verified and depending on this finding, the concept can be rejected or carried forward.

To do this type of research approach, two types of research methodology have been used, Qualitative Research Methodology and Quantitative Research Methodology, the following explain each.

3.3.1 Quantitative research:

Quantitative research is defined by Bryman and Bell (2007, p. 154) as '*entailing the collection of numerical data and exhibiting the view of relationship between theory and research as deductive, a predilection for natural science approach, and as having an objectivist conception of social reality.'*

The most popular research methods from this category are closed-ended questionnaires, experiments, correlation and regression analysis methods, and others.

For the purpose of this research two questionnaires were designed and the numerical data collected was analysed quantitatively using SPSS. The questionnaires aimed to reflect participant attitude and establish the level of satisfaction with the current medicine situation in Kuwait. The second questionnaire would focus on figuring out the availability of medicines Standards Treatment Guidelines in Kuwait public healthcare facilities. The questionnaires were conducted to gather a large amount of data in a relatively

short time; questionnaires, as a method of data collection, are considered preferable due to the confidentiality of the method, this will encourage participation and increase the level of reliability in the responses.

3.3.2 Qualitative Research:

The second method to be used for the purpose of this research is qualitative research, '*qualitative methods are often regarded as providing rich data about real life people and situations and being more able to make sense of behaviour and to understand behaviour within its wider context. However, qualitative research is often criticized for lacking generalizability, being too reliant on the subjective interpretations of researchers and being incapable of replication by subsequent researchers'* (Vaus, 2002, p.5).

The qualitative methods vary and come in many tools; for the purpose of this research, the methods used are interviews, document analysis and cross-comparison analysis.

The following will describe each qualitative method used.

3.3.2.1 Interviews

The second part of the research study is conducted by way of interviews; where the aim is to explore the attitudes towards the current medicine situation, and the perception of the senior healthcare managers towards an EML concept.

In the early studies the work is considered to be a baseline study or basic research, to improve the knowledge and get a feel of the current situation, without any particular purpose in mind.

3.3.2.2 Cross-Comparison

One of the objectives of the research is to gain experience from previous Essential Medicine List implementation procedures. For this reason a qualitative cross-comparison method is used to compare the procedures of various countries in their trip towards the implementation of the Essential Medicine List concept.

The comparative qualitative methodology was carried out between 5 international countries with different levels of income. The reason for this was to test the implementation processes from different perspectives and observe the transnational differences that these countries faced while launching their own interpretations of the Essential Medicine List. In order not to miss the finer details, that the research methodology might reveal, when countries with similar geographical and ethnical profiles were chosen, another comparison was carried out between all the Arab countries with an established or announced Essential Medicine List. This type of qualitative methodology was carried out because the Arab countries share similar ethnicity with the State of Kuwait; they have similar climate, some of them are very similar in terms of standards of living. By conducting this type of qualitative research, it's assumed that it might give an indication on what needs to be done in Kuwait once the Essential Medicine List has been adopted and implemented.

It was believed that this approach is a type of method that employs a multiple discipline in one study and that is what makes it flexible, but there are limitations to the technique which will be discussed later in the Methods Limitations section.

3.3.2.3 Visits

Several field visits have been conducted to two countries, one is Kuwait and the other country is the Kingdom of Saudi Arabia.

The reason for the visits is mainly because of the lack of resources and publications in regards to the Kuwait Health sector and lack of access to any literature to give a clear understanding of the health situation at a GCC level and at a more local Kuwaiti level.

3.4 Mixed Method Approach

The mixed method of data collection was necessary to enhance and validate the data and because the research question required this kind of approach. Conducting a mixed method approach will help in answering the research questions from various perspectives, it will help in ensuring the information gaps are minimised. The first parts of the research questions aimed

to investigate the health and medicine situation in Kuwait. In order to answer this question it was necessary to conduct a questionnaire and gain the views of the health professionals who are in close relation to medicine procurement. When moving to collect data on the health budget and Medicine budget in Kuwait, the only tool available was direct interviews.

The later part of the research questions were related to the EML implementation and what is likely to be expected when it's carried forward and becomes fully implemented in Kuwait. For this type of research question is suggested to be the best way to look at local, Arabic and International written and published material and documentations. This comparison has then been applied and aims to differentiate the hindrances that need to be accounted for when implementing an EML in Kuwait, and it helps to gain experience from other countries strategies and which will enable Kuwait to develop their own methods of implementation.

3.5 Methods Limitations

The qualitative research is challenging when it comes down to making prophecies and interpretations, it's time consuming and requires a very large number of resources to get to the information required. Very careful care needs to be practiced in order not to influence the results with personal biases and idiosyncrasies.

A major limitation was found when conducting the visits, as seen especially within The Kingdom of Saudi Arabia; the local culture and the limitation of women, made access to various departments and thereby the data collection process very difficult and challenging.

Another common limitation found when conducting the qualitative methodology, was that the data extracted from different countries did not use similar terminology and even more research and time was spent extracting the required data.

3.6 Organisation Studied

The research was approached at three different levels; the first level was the international level, to help in understanding the concept of the essential medicines list internationally. By exploring the concept internationally it's proposed that it will help in gaining experience from these countries methods in the implementation of the Essential Medicine list. In having awareness to the various processes used by different countries. It also may give an idea on what is the most suitable method in implementing the Essential Medicine concept in the State of Kuwait. It's proposed that if the international health organisation techniques were studied, it might assist in extracting interpretations to the difficulties they have undergone, and their methods of overcoming such issues. It's proposed that by studying the Essential Medicine List concept internationally, it will give some direction as to the best possible way to approach the process of introducing the Essential Medicine concept. It will provide knowledge to carry it forward and convey a perception of what might rise as an obstacle; it's proposed that it might give an indication on the best plan to introduce the concept of Essential Medicine.

The second level of the study was carried out to investigate the Arabic countries' Lists of Essential Medicines; this part has taken place due to the fact that the Arab countries share similar health profiles and ethnicity, they are similar in terms of climate, but they differ in the level and standards of living. For this reason all the Arab countries that have a list of Essential Medicine were included, the idea behind such an approach is to view all levels of income experiences with the list; how they managed to make it operational, how they overcome the various issues with stakeholders, that are usually resistant to any changes that might have an effect over their interests.

Finally, fieldwork studies were carried out in Kuwait in person, and a large number of Healthcare facilities and organisations have been visited, this was the case because in Kuwait, very few to almost none, of the information and figures are accessible online. Generally all data is available in the form of hardcopies and the process of obtaining approval to gain access was quite lengthy and the bureaucracy was exhausting. This part of the research was

carried out to gain awareness of; the current medicine situation at the state of Kuwait, the health needs of Kuwait, disease profiles, the available guidelines and regulations, current health policies, the process of introducing new policies, Kuwait Ministry of Health general budget and the public sector medicine budget, medicine catalogue, medicine consumption rate, procurement cycle, references available to the healthcare professionals, Quality Assurance and Quality Control process, medicine registration process, withdrawal of medicines, pharmacovigilance availability, health transparency and medicine corruption.

The research work in Kuwait was carried out at various levels, it started at a high ministerial level, this is important to gain clearance to proceed and get the required information from different departments. Various Undersecretaries (the term for the highest operating managers) have been engaged in personal meetings, such as; Dr Waleed Alfalah, Undersecretary of Development and Quality at the Kuwait Ministry of Health and Dr Omar Alsayed Omar, Undersecretary of Medicines and Medical Appliances.

At a more academic level, a meeting was held with Dr Mohammad Wahede, Associate Dean at the Faculty of Pharmacy, at Kuwait University. The reason for this meeting was to gain the academic view of the general situation of medicine in Kuwait and because the Faculty of Pharmacy is the only source of a pharmacist training centre in Kuwait. It was considered important to get the Faculty of Pharmacy involved in the concept as early as possible, because when the Essential Medicine Concept becomes a reality, it will be explained and taught at the Faculty of Pharmacy to pharmacy students.

At a lower level, various managers were met with and documentation was obtained to be included in the research and clearance to work in other departments was granted, through these managers. These managers included the following; Pharmacist Essam Alsultan, Head of Pharmaceutical Department at the Psychological Hospital (Secondary Healthcare hospital) and pharmacist Asma Al-Mutairi, Pharmacist in-charge of Ashbelia Polyclinic pharmacy (primary healthcare Centre), both are directly involved with the medicine procurement.

Chief Pharmacist Fahad Al-Qatan, Special Medicines Department Manager at the CMS, and at Kuwait FDA, the head of the New Medicine

Registration and Listing Department Dr Dina Bustaki, and the Head of Quality Control and Quality Assurance and Laboratory Dr Sarah Maqseed, were both interviewed to provide information in regards to their departments. At a lower level at the FDA, Pharmacist Izhar Al-Ostath, pharmacist in-charge of New Medicine Registration was interviewed. Pharmacist Joseph of the Reviewing of New Medicine Department and the staff of the Pharmacovigilance Department were also included in the interviews.

The following Figure 3.1, summarise all levels.

Figure 3.1: The Organisation levels that been studied

3.7 The Philosophical Paradigm of this Study

Guba and Lincoln (1994), divide research philosophies into four paradigms, which are Positivism, Postpositivism, Critical Theory and Constructivism (Interpretivism). Guba and Lincoln state that these paradigms have been challenged, until recent years. This is true for qualitative research, in order to gain its position as being the paradigm of choice, for reporting, informing and guiding as well. Paradigms have been described by Guba and Lincoln '*as a set of A paradigm may be viewed as a set of basic beliefs (or metaphysics) that deals with ultimate's or first principles. It represents a worldview that defines, for its holder, the nature of the "world," the individual's place in it, and the range of possible relationships to that world and its part.*'

Guba and Lincoln (1994), state that each paradigm has three elements, the first element is the ontology which is the ''truth'' that is being investigated and researched. The second element is the epistemology, which is described by Guba and Lincoln (1994) as the relationship between the truth or reality and the researcher. The final element is the methodology, this can only be described as the procedure that is being used to investigate the reality.

The following will give a brief description of each paradigm, and will indicate the best research paradigm that can describe this particular research.

3.7.1 Positivism

Positivism assumes that phenomena can be accurately defined and measured (normally quantitatively). It provides a single, and unbiased view of reality (Carson *et al.*, 2001). It can be defined as being the philosophy of knowing. In this type of philosophy, the researcher role is basically data collection and interpretation of the findings. Usually in such models the findings are visible and measureable.

Some researchers assume that positivism is not a suitable method to measure human responses and life experiences. (Healy & Perry. 1997). It's a suitable paradigm in science, if that particular method of science can be

measured qualitatively. It is considered not to be a suitable means of measuring reality in a social sciences situation (Guba and Lincoln, 1994, p. 110).

From this definition of the positivism paradigm, and since the study focuses on researching healthcare professionals' attitudes towards the medicine situation and researching the policy makers and senior health managers' behaviours towards the introduction of new policy, this type of paradigm is not a suitable paradigm to this particular study, simply because there is no expected response reality of the interviewee and the participant's reaction cannot be anticipated or predefined.

3.7.2 Postpositivism

Postpositivism believe that a reality exists, like positivists do, though they hold that it can be known only imperfectly and probabilistically (Robson, Colin. 2002). Postpositivism came, in a way, to criticise positivism, because no phenomena are 100% rock-solid, it can be described as being an amendment of positivism. In another way it's a more flexible paradigm than positivism. Postpositivism still fails to address human attitude and behaviours, for this reason it fails as a paradigm to explore the research questions of this study.

3.7.3 Critical Theory

Critical Theory is a type of paradigm that focuses on criticism and trying to alter society. It's been developed by the Frankfurt School, which is not an actual school, it's more a group of scholar's thoughts (Heal and Perry, 2000).

For the purpose of this research, this type of paradigm is not suitable and doesn't tackle the research questions because this research study doesn't intend to alter any society and doesn't criticise any particular society.

3.7.4 Constructivism (Interpretivism)

Guba and Lincoln (1994), define Constructivism as a paradigm that refers to a particular belief-system, and is held in a particular context. Some researchers, in the field of research philosophy, refer to Constructivism as Interpretivism; it is a method of multiple realities as explained by Lincoln and Guba (1998). This paradigm integrates human interest into the study,

Interpretivism was explained by Collins, (2010, p. 38) as being '*associated with the philosophical position of idealism, and is used to group together diverse approaches, including social constructionism, phenomenology and hermeneutics; approaches that reject the objectivist view that meaning resides within the world independently of consciousness*.'

Hudson and Ozanne (1988) state '*that the researcher inter the study with a prior insight of the research context but assumes that this is insufficient in developing a fixed research design due to complex, multiple and unpredictable nature of what is perceived as reality'* (Hudson and Ozanne, 1988).

Carson (2001) explains Interpretivism as being personal and can be adopted to form a more flexible research structure, and avoid rigid structural framework that is found in positivist research.

In summary, the interpretivism research paradigm is a form of philosophy that is able to understand and get interpretation of the meaning of human behaviours', without focus and no prediction of the causes and effects (Neuman, 2000; Hudson and Ozanne, 1988).

The philosophy of this research is considered, interpretivism philosophy, where interpretivists believe that the reality is relative and multiple. According to this tradition there can be more than one reality and more than a single structured way of accessing such realities (Lincoln and Guba, 1985). In order to carry out this exploratory work which is often based on field work, observation, the methodology used is surveys and/or interviews which are cross-sectional (Livesey, 2006).

3.8 Strategies and Research Design

The following section will explain the process of data collection, the pilot stage, the rationale behind using this type of data collection and methodology and sample selection and the justification of sample selection.

3.9 Research phases

3.9.1 Pilot Study

A pilot study was carried out at the very early stage of the research, the two questionnaires were both piloted with a small group of participants to confirm the efficiency of the instrument being used and to help in modifying any confusing or imprecise questions. It aims to observe where the data gathering method is reliable and accurate or need improvements and modifications.

By conducting a pilot study, it was hoped that it would reveal any faults or weakness with the study design. It is also intended to approximately predict the time scale required to complete the questionnaire. It helped in predicting the best method to introduce the questionnaire to maximise participation and responses.

Overall, the pilot study is a justification of the methods and tests its reliability.

3.9.1.2 Pilot Study Limitations

Although the pilot study helps to identify the parameters mentioned earlier, it also has major limitations, as it can successfully hide issues that may arise in a large scale study. Such issues are the number of personal required to work on the study to cover the required large number of participants, and most importantly it will not address the issue of the handling, organising and analysing of the large data collection that will be generated from the main study.

3.9.1.3 Pilot Study Sample Size

Connelly (2008) suggests that the sample size should be 10% of the population of the larger study. Where Isaac and Michael (1995), suggest 10-30 participants, this is agreed by most researchers in the field, such as Julious (2005), Treece and Treece (1982).

The first pilot study was conducted with a group of 10 Pharmacists, to test the validity of the first questionnaire ‘the Current Medicine situation at the State of Kuwait’; the responses were not included in the actual data collection of

the project. With regards to the second questionnaire 'the presence of standard treatment guidelines at Kuwait MOH healthcare facilities' another 5 pharmacists and 5 doctors where approached and took part in the pilot study, the responses were again not included in the final data collection and were not analysed.

The reason for choosing a smaller number of participants for the pilot study, is because Kuwait is a small country with a population of 1.3 million, the number of pharmacists in the public sector is very small, around 400 pharmacists, and the medical staff that is involved in the procurement of medicines is also small.

3.9.1.4 Pilot Study Outcome

The outcomes of the participants' views were considered and changes were made to the process of gaining access to the willing participant. It became clear that the best way to find a willing participant was if they were in a group, and during a break, this was the reason for approaching participants who were on a short break, between workshops or medical lectures. It was discovered that if one candidate agreed to participate the rest of the group would agree to take part.

It was also found that it is often best for more than one person to approach the participant, this is evident by the fact that more responses were gained when each person approached different groups and it also saved time.

3.9.2 Data Collection and Analysis Methods

All the data collection processes were carried out in Kuwait and one visit to Saudi Arabia, it was collected in the form of two questionnaires and several interviews with Under-secretaries and Senior Health and Budget Managers. The second part of the data collection was aimed to perform a cross-analysis between different existing EML's, at an Arabic level and International level.

The data was generally collected in person, all the interviews were carried out by the researcher of this study. In order to speed up the process and gain more data, the questionnaire part, required help from two other colleagues in the Ministry of Health in Kuwait.

The interview participants were contacted in several ways, some were contacted by email, phone, through the social media-WhatsApp application and through arranged appointments with their secretaries in person. All interviews were recorded for later referral and analysing. The questionnaires were handed to the participants in person and returned inside a sealed envelope to enhance confidentiality.

The cross-comparison table information were gathered from various resources, some from governmental official web pages, WHO library, GCC official Library, online publications and previous studies.

3.9.2.1 Analysing tool

3.9.2.1.1 Questionnaires Analysing Tool

SPSS was used for both questionnaires; it's an abbreviation for 'Statistical Package for the Social Sciences.' This package was selected based on the familiarity with the statistical data analysing package, the practicality of manually entering the data, and the ability to edit data easily and from various sources.

Another practical reason for choosing SPSS is because it doesn't require definition of variables manually. It also offers a great range of graphs and charts, and the output and results are stored in a separate file from the data itself.

The limitation of the SPSS method of analysing the data, was mainly found in the lack of evaluation of how well the data is represented. Another limitation was not being able to use it in any computer; it can only be uploaded to one computer and used on that one.

3.9.2.1.2 Interviews Analysing Tool

The primary reason for using interviews is because they will provide more in-depth information than surveys, because the population of the interviewee were mainly senior managers and under-secretaries, it was the most appropriate method for such situations and more suitable to their status. It

permitted asking further questions spontaneously and gave the participants the chance to express their views freely.

3.9.2.1.3 Qualitative Coding & Analysis

This type of analysing tool is ideal to analyse interview transcripts, codes can be based on themes, topics, ideas, concepts, terms, or phrases. It transfers information and prepares it into a form of understandable data using computer software.

Iain Hay (2005), outlines a two-step process beginning with basic coding in order to distinguish overall themes, followed by a more in-depth, interpretive code in which more specific trends and patterns can be interpreted.

This process can be done with several computer software, such as Atlas.ti, QDA Miner and Nvivo, but it can also be done manually. This is possible by highlighting the concept with different colours and analysing them further.

Interview data can be coded in three ways, Open Coding, Axial Coding or Selective Coding. The following explains each coding;

- **Open Coding**

Open coding focusses on the text and categories it into primary level and secondary level. The primary heading or level in this research is the EML and the subheading would be its value to the medicine situation in Kuwait.

In other words, the data obtained will be divided into segments then inspected for common theme, keywords or phrases. The way this data is obtained is by asking questions, making comparisons and looking for common ground between responses.

- **Axil Coding**

Axil coding differs from open coding in the way the responses are interpreted, it's more related to using your own concept and categories to analyse and read the results rather than allowing the data to reveal its own

theme. This coding might be suitable to different types of research but it's not suitable to this particular study because this study when conducted did not have any prior expectations or opinions on the matter.

- **Selective coding**

The third type of coding, is selective coding, which selects a main category then relates it to the other categories. It's suitable is generally for making a type of storyline to describe an occurrence. For this reason, it was not used in this research.

In addition the Limitation is that the method is considered time consuming and labour intensive.

3.9.2.1.4 Comparative Research Method Analysing Tool

The comparative approach was used because it can best, to clearly identify the differences and similarities between nations. It's defined by D.E.Sanga (2004) as '*a research methodology in the social sciences that aims to make comparisons across different countries or cultures*.'

For the first comparative study, 5 countries where selected, from different continents with different levels of income and different levels of development and access to resources. The reason for this is because Kuwait is a wealthy country, similar to Norway, with high access to various international resources and technologies similar to the developed countries such as Australia. At the same time Kuwait suffers from bureaucracy and resistance to change, which is found in the less developed countries such as India, Sri-Lanka and Bangladesh.

In the second comparative study the choice was based on geographical location and ethnicity, all the countries in this study are Arab countries with similar ethnicity and relatively similar health issues, but they all have various income levels.

The analysing tool of choice was a comparative tables that demonstrates the required data simply and clearly; this was put together following intensive document review.

3.9.2.2 The General Sampling Process

The sampling methods vary depending on the type of research being carried out, and the method used. For example a survey that contains a large population has a different form of sampling than interviews that have fewer numbers of participants. The choice of the sample population will differ in accordance to the method being followed and the purpose of the study. The following explains each sampling method used in this research.

- **Questionnaire Sample Selection**

Sample selection is the principle used to target the most appropriate population to take part in responding to the questionnaires. When conducting the sampling process a few points need to be considered, these are the size of the sample, which needs to be manageable, the target population, which needs to be able to provide insightful and meaningful data and the participants need to be involved directly with the topic being researched. For these reasons, when selecting the population, for the first questionnaire, only health professionals, who are directly involved with medicine procurements, were included. The reason behind this, is that they can provide a very realistic and honest opinion to the actual medicine supply system in Kuwait. The participants were all from Kuwait, simply because the research aims to implement the EML in Kuwait.

The sampling method can be divided into two methods, Probability Sampling Methods and Non-Probability Sampling Methods. The basis of these methods is explained below.

- **Probability Sampling Methods (PSM)**

In this type of sampling, participants have exactly the same chance of taking part; it has a subdivision of simple PSM, stratified systematic PSM, Multistage PSM and Cluster sampling.

- **Non-Probability Sampling Methods (nPSM)**

In this type of sampling methods, not every member of the population will take part, but they are selected in a non-random manner based on judgment, quota, convenience and extensive sampling.

For the purpose of this study, the sampling choice was clearly the Non-Probability sampling methods, simply because not all of the pharmaceutical staff and medical doctors were involved in the questionnaire. It was a type of Judgement Sampling because the participants were chosen in relation to their direct involvement with the medicine supply cycle.

- **Interview Sample Size and Selection Purpose**

The interviews were carried out with two purposes in mind, the first to gain the general response towards the EML implementation and the second, to explore the medicine situation at Kuwait MOH. The first aim was carried out with Dr Waleed Alfalah, Undersecretary of Development and Quality at Kuwait Ministry of Health and Dr Omar Alsayed Omar, Undersecretary of Medicines and Medical Appliances, and at a more academic level, Dr Mohammad Wahede, Associate Dean at the Faculty of Pharmacy, at Kuwait University. The staff of the Ministry of Health, which have a more direct interaction with medicines handling and procurement, were also involved. Three interviews were carried out with, Pharmacist Essam Alsultan, Head of Pharmaceutical Department at the Psychological Hospital (secondary Healthcare hospital), Pharmacist Asma Al-Mutairi, Pharmacist in-charge of Ashbelia Polyclinic pharmacy (primary healthcare Centre) and Chief Pharmacist Fahad Al-Qatan, Special Medicines Department Manager at the CMS.

The second part of the interviews, were aimed at exploring the medicine situation in Kuwait public health sector. For this reason, staff from different departments were met with, in order that they could explain each experience of the medicine situation at the state of Kuwait, each in accordance with his/her expertise. The samples selected have various pharmaceutical background, which will help in exploring the medicine situation as a whole and from different perspectives. The candidates were the head of the New Medicine Registration and Listing Department, Dr Dina Bustaki and the Head of Quality Control and

Quality Assurance Laboratory Dr Sarah Maqseed. At a less high level, at the FDA, Pharmacist Izhar Al-Ostath, Pharmacist in charge of new medicine registration was interviewed. Pharmacist Joseph of the Reviewing of New Medicine Department and the staff of the Pharmacovigilance Department were also included in the interviews.

3.10 Ethics, Reliability, Validity, Generalisability and Limitations

The following section describes the strength of the research methods used to answer the research questions.

3.10.1 Ethics

Ethics approval has been granted by the Chair of the Biomedical, Natural and Physical Research Ethics Panel at the University of Bradford on 18th June 2014. The data obtained was treated with strict confidentiality and no participants were identified when doing the survey. In relation to the interviews all participants were asked if they would like their names to be included in the research, they all gave consent, this was all recorded on a mobile and they were all fully aware of the situation. All the required clearance was obtained in Kuwait to get the required information.

With regards to the data obtained in Kuwait, all the required official procedures were followed and all the information release forms were granted.

3.10.2 Research Study Challenges

The study was challenging, to be able to obtain the required documentation and records, the researcher needed to be fully involved in Kuwait Health system. The researcher needed to have the right acquaintances to be able to speed-up the process of obtaining data. The interviews conducted with the Undersecretaries were very difficult to arrange and required being in a close affiliation with the Undersecretary or being able to get access to arrange an appointment; this was similar with the rest of the Senior Managers. For another researcher to do similar work, that researcher needs to be certain of his or her network, otherwise it will take an extremely long time to get access to the correct person.

3.10.3 Reliability and Validity of the Study Methods

The method needs to demonstrate validity and reliability, this is considered by the researcher as the fundamental of any research; otherwise the methods are not dependable. What is meant by reliability is that the results obtained are reproducible and not a onetime finding. In other words, if some other research was going to follow the same research methodology, it should be able to reproduce similar results. Validity refers to the strength of the test measures (Martyn Shuttleworth. 2008).

Validity has several types, the first type is the external validity and it's related to the generalization of the process used, which can be subdivided into population validity and ecological validity (Martyn Shuttleworth. 2009). The second type of validity is the internal validity; this ensures that the design of the experiment is related to the cause and effect of the research (Martyn Shuttleworth. 2009). There are other subtypes, such as; test validity, criterion validity, content validity, construct validity, and face validity (Martyn Shuttleworth. 2009).

To ensure the validity of this particular research, the goals and objectives are well defined and close care has been taken not to divert from them. The assessments methods used are being selected to demonstrate the aims and objectives.

It's important to mention that this study is designed to test the Kuwait Medicine situation. It is aimed at finding out the available guidelines and policies, and trying to figure out an appropriate recommendation on how to launch and implement the Essential medicine list. The study also observed the established Essential Medicine Lists at an Arabic and international level. The information gained from this study can be applied to future comparative works but not the exact application of the study design. If the work is carried out in Kuwait, for this research to be considered reliable, the results need to be reproducible.

3.10.4 Reliability of the Research Methods

'The Free Dictionary', defines reliability as "*Yielding the same or compatible results in different clinical experiments or statistical trials.*" It's a very important measure and researchers need to be fully aware of it. Reliability at a scientific setting are expected to reproduce similar results with slight variations, on the other hand in social sciences that is not the case. The reason is because in social sciences setting, there are uncontrollable variables and some factors are random (Martyn Shuttleworth, 2009). Testing reliability can be achieved using the Test-Retest Method; this is done by conducting the same measure at a later time.

Another way we can measure reliability is by using the Internal Consistency Test; this is achieved by comparing two different methods to test the same concept. Because Reliability is very important, pre-tests are always involved and that is another reason for pilot studies.

3.10.5 Generalisability of the Methods

The results obtained are related to the Kuwait medicine situation but the testing methods can be used for other countries. This study totally focused on the medicine situation in the public sector of Kuwait, the findings are only true to Kuwait, but if, another researcher used the method to examine other countries medicine situation it would be appropriate, with adjustment. The reason being is that the Kuwait medicine situation is unique to Kuwait, it's a wealthy country with great access to great resources, but there are a lot of bureaucracy that causes obstacles. This was established from the literature review carried out in relation to Kuwait, it's been found out that there are a lot of dated regulations and at the same time they are very strict, and need to be followed to introduce any policy. For this reason the method is relatively general to be used by other countries to measure their health situation and to try to introduce an Essential Medicine List, but modification is still required.

3.10.6 Limitations of the Methods

The study was limited to Kuwait only, but data from other countries was also used to gain experience and knowledge of the previously implemented

Essential Medicine Lists. The study purposely focused on healthcare professionals and excluded healthcare recipients. The reason for this, being because Healthcare recipients lack knowledge of such concepts and lack the appropriate information in regards to the survey questions, because they are not involved in the procurement and purchasing of medicines and not aware of the process of quality control and quality assurance of medicines which need to be the major focus when procuring medicines.

3.11 General Research methods

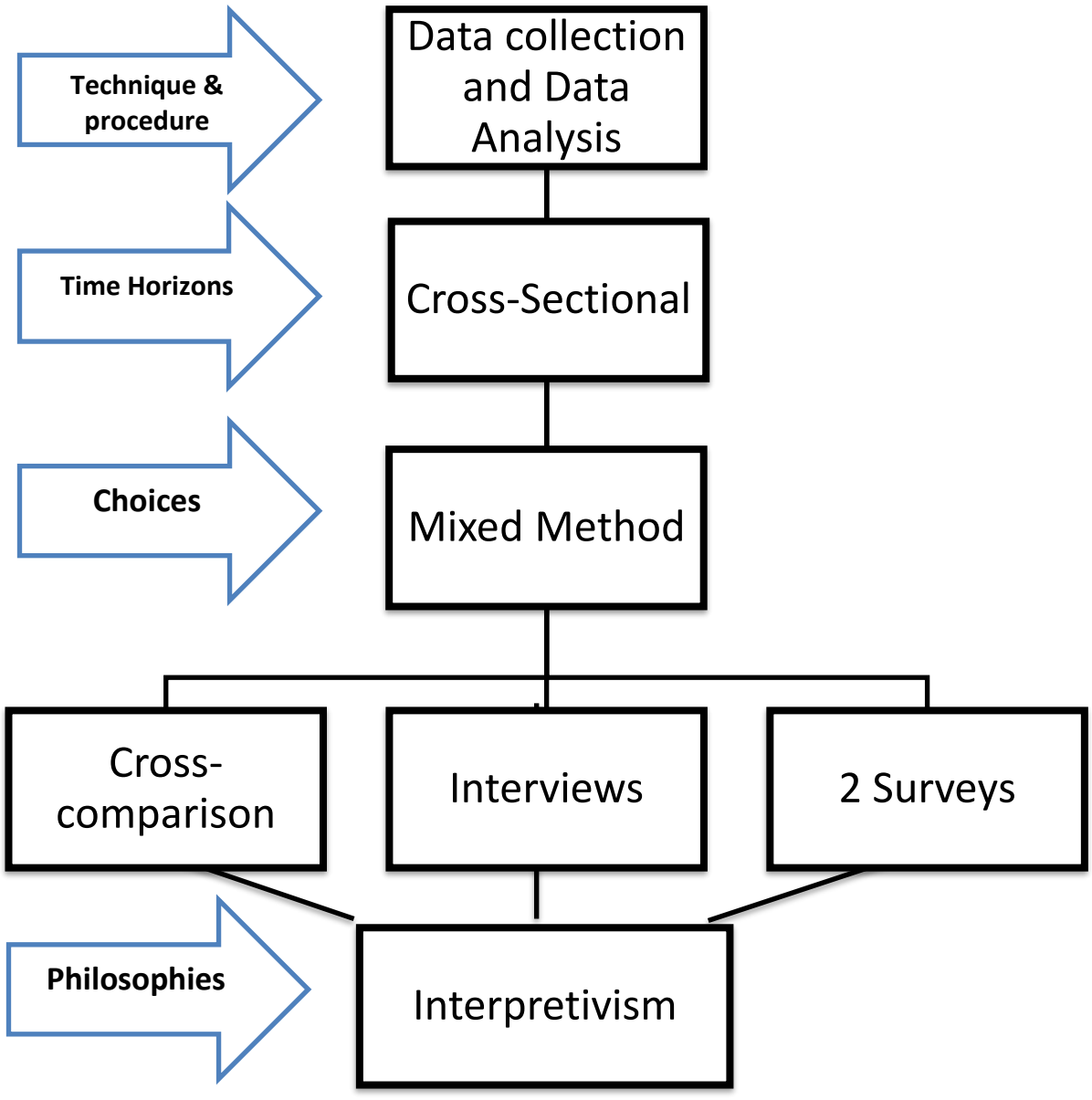
In general, the research methods are summarised by the following flow chart.

The survey carried out, in this case, involves selecting unbiased samples of participants closely involved in the medicine supply chain in the state of Kuwait.

The method of collecting data composes of two parts, the first part was two questionnaires handed to the participants directly, and the second part was through direct interviews with senior healthcare managers.

The study is considered cross-sectional because it involves participants from different medical backgrounds, different work experience and different organisations.

Figure 3.2: General Research methods



3.12 Fieldwork Report

The fieldwork of the whole study was carried out over a period of three years (June 2013 until September 2015), this was the case because the research required different methods. In the first year it was exploratory work, to view the current medicine situation in Kuwait public health facilities and to explore the availability of Standard Treatment Guidelines, which is vital component for any EML. Later, it moved towards viewing the policy making process and how it's possible to implement this concept with well-informed background information on what to expect as concerns or gains. The work then focused on the Arabic countries' experience with the EML concept and how these countries managed to present a suitable EML.

3.13 Questionnaires Design

When designing the questionnaires several points needed to be considered and many steps were attempted to design significant questionnaires. The first point is to decide on the information required clearly and specifically, in this case it was the medicine situation in Kuwait and the availability of Standard Treatment Guidelines.

Following this step, the target respondents were decided; both questionnaires needed to include healthcare providers that are in direct contact and involvement with the medicine supply in order to give a valuable response that is closely related to the actual situation. The healthcare recipients were deliberately excluded due to their lack of knowledge to the aims of the questionnaires, hence they will not provide any meaningful data.

The method of choice to reach the target audience was decided and explained earlier, by approaching them in person and directly, the reason being that when emails were sent, there was no response/reply.

When designing the questionnaires, the question choices were carefully selected, they were clear, direct and relate fully to the research questions. The length of the questionnaires and number of questions in each questionnaire were not many, this was done to enhance response rate and encourage participation.

The questions were all multiple choice type; it having been found out that participants prefer these type of questions because it takes less time to complete. But there was also, an open question to allow the participants to express their opinion if they felt the need to.

3.13.1 The Current Medicine Situation at the State of Kuwait Questionnaire

The questionnaire was limited to 8 questions to increase the response rate. The questions were purposely brief and direct. The questions were all multiple choices except of 2 questions that gave the participants the chance to explain their own concerns with a section at the end to give the participant the chance of adding views to the topic being discussed. The following table represents the questions, choices and the focus of each question.

Table 3.1: Questionnaire 1; Assessments of the Current Medicine Supply System in the state of Kuwait, and the medicines regulatory system. healthcare provider's views on the concept of Essential Medicines List

Question	Question Focus
How long have you been working as a healthcare provider	Focus on work experience, to compare old school with new generation views.
Speciality	To find out if speciality variation has different opinions.
Are you satisfied with the current medicine supply system	Examine the level of satisfaction.
Do you think the medicine supply system is well regulated	Focus on the dated regulation and see if the participants think new laws need to be in place.
In your own words, how do you think the medicine supply system can be improved	Open question to allow expression of own thoughts.
If a generic drug has proven to have good quality and efficacy, to what extent would you prescribe it	How well generics are accepted.
What are your views on the establishment of 'Essential Medicine List' program at the state of Kuwait	This will allow a preview of what might come up as objections or acceptance to the concept in the future, and there was a space to allow further explaining of thoughts.

3.13.2 Standard Treatment Guidelines Questionnaire

The second questionnaire aimed to investigate the presence of Standard Treatment Guidelines at Kuwait MOH healthcare facilities. The questionnaire included 6 questions only.

The questions focused on the type of healthcare facility, participant work experiences, participant STG currently followed, the reason behind using such STG, and are they aware of their colleagues STG. The questionnaire population were all medical doctors. The STG was investigated at all healthcare levels, at the primary healthcare facilities, secondary healthcare facilities and tertiary healthcare facilities. The participants were contacted directly, at their work place and a small group were contacted by phone, their responses were completed from their comments.

The following table represents the question choices and the focus of each question.

Table 3.2: Questionnaire 2; Assessment of the availability of Standard Treatment Guidelines in Kuwait Healthcare Facilities.

Question	Question Focus
The Healthcare facility type involved.	To find out which level of healthcare is more up to date.
Duration of work experience at the current healthcare facility.	Focus on how the experience of the healthcare provider effects their STG.
Are you aware of the Standard Medical Treatments Guidelines (STG) of your Healthcare facility?	Focus on the efforts to make STG, and how well they would be followed if they existed.
What type of STG do you use?	Open question, allow to demonstrate the type of STG used.
Are you using the same STG as your colleagues?	Measure the level of awareness and involvement in the work place.
Why using this specific type of STG?	To understand the variety of STG available.

3.13.3 Time Frame

It took 12 weeks, excluding Fridays and Saturdays, public holidays of Kuwait, to complete the questionnaires.

3.13.4 Confidentiality and Consent

The questionnaires, although handed in directly to the participants were later returned in a sealed envelope to ensure confidentiality, a consent form was handed in to the participant to explain their rights and the right to withdraw from taking part at any time. The consent form is in appendix I.

3.13.5 Location of the Questionnaires

The questionnaires were all carried out in Kuwait, simply because the study is related to Kuwait and investigates the medicine situation in Kuwait public healthcare facilities.

The questionnaires were conducted in primary, secondary and tertiary healthcare facilities; this was the case to ensure the required information was gained from all the healthcare levels available in Kuwait Public Health Sector.

The following is a list of the healthcare facilities involved in the questionnaire.

- Ashbelia Poly-clinic (primary healthcare)
- Dasman Poly-clinic (primary healthcare)
- Mubarak Alkaber University teaching Hospital (secondary healthcare)
- Ibn-Sina neurological hospital (tertiary healthcare)
- Al-babtain Burn and correction surgeries (tertiary healthcare)
- Al-bahar Ophthalmology Hospital (tertiary healthcare)
- Zain ENT Hospital (tertiary healthcare)
- Psychology Hospital (tertiary healthcare)
- Kuwait Cancer Research Centre (tertiary healthcare)

The questionnaires were later tested and two pilot studies were conducted, the following explains each study.

3.13.6 Pilot Questionnaires

Once the questionnaires were fully completed, both questionnaires went through a pilot study to examine their suitability and practicality and to amend any questions that might be confusing or unclear. It involved testing each questionnaire with 10 participants. The pilot study revealed the need to adjust a question and delete another.

3.13.7 Data Collection – Questionnaires

At the initial stage of the questionnaires, it was attempted to email the required participants, it took a long time to get the required emails, about 50 emails were sent and unfortunately no responses were received. Upon enquiry about the lack of replies, it's been found out that almost most the people contacted by email don't check emails regularly, and some of the emails are closed because they are not being used and not checked regularly. It might seem unlikely in any developed country that educated people are not checking their emails regularly but it is common in Kuwait where people prefer to use smart phone applications to communicate even at a professional level; if there is a need to communicate officially, emails are not acceptable and only official letters and hard copy memos are accepted. For this reason, the participants were contacted in person and the help of two other colleagues were sought to speed up the process of data collection.

3.13.8 Questionnaires Participants

The target groups were physicians, because it was expected that they would be affected by the list greatly and their patients are concerned with any changes to the supply chain.

The second group were academic staff at Kuwait University, because they are involved in teaching the student the concepts and their views do matter.

The next group were Central Medical Store staff, and their involvement would obviously be in procuring the medicines and they are dealing with the majority of the medicine supply cycle.

The fourth group were public sector pharmacists, they were included because they are the last people before the public that deals with the supply of medicines and public complaint or appraisal.

3.14 Interviews

Kvale, 1996, define interviews in Qualitative research as a tool to *'describe central themes and the meanings of it in the life world of the subjects. The main task in interviewing is to understand the meaning of what the interviewees say.'* (Kvale,1996).

McNamara, 1999, states that '*Interviews are particularly useful for getting the story behind a participant's experiences. The interviewer can pursue in-depth information around the topic. Interviews may be useful as follow-up to certain respondents to questionnaires, e.g., to further investigate their responses.' (McNamara,1999*).

It's generally known that interviews are more personal than questionnaires, it provides direct interaction with the interviewee, it helps in further investigating the researched topic; on the other hand they are time consuming and require a certain level of skill.

Interviews can be conducted in several ways; the following is a short description of each;

- Informal or conversational interview, (No pre-set questions).
- General interview guide approach, (there is a guide approach with a degree of freedom).
- Standardised, open-ended interview (set of open-ended questions asked for all).
- Closed, fixed-response interview. (Pre-set question with multiple replies to choose from).

For these particular research interviews, there were two sets of interviews; the first set was the standard interviews with pre-set questions. This

was chosen to ensure adherence to the objectives of the research questions, appendix IV.

The second set of interviews that were conducted to gain information used the general interview guide approach. This is intended to extract the knowledge from the participants in specific areas and allows them to express and share as much information as possible; this method was useful due to the fact that there was a lack of published information in regards to Kuwait health and medicine budget statistics, health policies availability and quality assurance techniques.

3.14.1 Development of the Interview Protocol

There were two interview protocols to ensure coverage of the research questions, the first interviews aimed to explore the following research question,

- What are the contextual factors in Kuwait which would assist or hinder effective implementation of EML?

The interview protocol contained open-ended questions to allow the interviewee to express his/her opinion fully.

Several meetings and interviews were conducted with senior managers at the MOH and Kuwait University, Faculty of Pharmacy. The meetings and interviews were carried out with the following;

Dr Omar Alsayed Omar, Undersecretary of Medicines and Medical Appliances. His long experience with the medicine supply chain and all the issues with the pharmaceutical services both in terms of private sector and government sector would be beneficial to the work being carried out.

Dr Waleed Alfalah, Undersecretary of Development and Quality at Kuwait Ministry of Health. His area of expertise aims to improve the healthcare services at the state of Kuwait.

Dr Mohammad Wahede, Associate Dean at the Faculty of Pharmacy, Kuwait University. University of Kuwait resources are of great value to the research. Many unavailable online.

Chief Pharmacist Fahad AlQatan, Special Medicines Department manager at the CMS. He is directly involved with the majority of the procurement of medicines and supplies all levels of MOH healthcare facilities, Ministry of Defense Hospital, the National Guard Hospital and the ministry of social affairs centres. The medicine list and the consumption rate of medicines are very important for the purpose of this research. Dr Al-Qatan was kind enough to provide the data related to handling and procurement of the medicines at the CMS.

Pharmacist Essam Alsultan, Head of Pharmaceutical Department at the Psychological Hospital (secondary Healthcare hospital). And Pharmacist Asma Al-Mutairi, Pharmacist in-charge of Ashbelia Polyclinic pharmacy (primary healthcare Centre). Both are directly involved with the medicine procurement.

Ministry of finance, national budget division. The aim of the visit was to obtain the proposed MOH budget and the actual MOH budget.

MOH Budget analyst, the contact aimed to obtain what percentage medicines represent in comparison with the total MOH budget.

Several approaches were followed to contact the persons taking part, but mainly they were spoken to over the phone and arrangements were made for a suitable time to meet with them. On a few occasions when the persons' number was not available, a meeting was arranged through their office, by going personally to the secretary and asking for a meeting.

The second part of the research adopted a casual, informal and more conversational interview, this was important to describe the following;

- The policies that are being established in Kuwait,
- The type of protocol being followed,
- What are the end results?
- Are they operational?

These interviews were conducted at Kuwait FDA, it was carried out at the new medicines registration department, the laboratory and quality assurance department and the newly established pharmacovigilance section.

3.14.2 Management of Interviews

The interviews were all conducted in Arabic and then translated into English. A transcript was later sent to the interviewees to verify the content, but no response was received. Later visits were therefore, made in person, to confirm the content of the transcripts, and it was read to the interviewees and consent was given.

The later part of the research was focused on gaining background information on the Kuwait health situation and the Gulf Co-operation Council countries, the information was not available online and not published thereby requiring personal presence to access the hard-copies of the required data. For this reasons several visits were made to gain the required information.

3.14.3 Interviews Preparations

The location of the interview needs to be selected carefully to ensure continuation and no distraction; the purpose of the interview was fully explained to each participant. The confidentiality terms were discussed and consent was given, the interview format was explained fully and questions and queries were encouraged, all interviews were recorded after taking permission from the participants.

3.15 Visits

Visits were carried out for the purpose of this research, few were local in Kuwait and one was to Riyadh in the Kingdom of Saudi Arabia.

These visits included the Arab Planning Institute-Kuwait, where there is a large library with several Arab health economy references, the majority in Arabic language.

Visits were conducted to Kuwait Ministry of Finance to obtain the proposed and Actual Ministry of Health date.

Visits to Kuwait M.O.H to the budget Department and finance, to the CMS, and to the FDA.

The second major visit was to the GCC council in Riyadh, which was faced with hindrances due to the local laws of the region, as a result I was not allowed admission to the GGC headquarters, but Professor Tawfik A M Khoja, Director General Executive Board, Health Ministers Council for Cooperation Council was kind enough to communicate with me and provided the related health data for the GCC countries

3.15.1 Limitation of the Visits

The visits conducted in Kuwait faced a number of changes through rescheduling and delays, but were achieved after several attempts.

The visit to the Kingdom of Saudi Arabia was very challenging, and I was refused admittance to the GCC building because I'm a woman and the building was men only. At a later time Professor Khoja was kind enough to meet at another location which is King Saud University to provide me with the required data.

3.16 EML Cross-Comparison Methods

The third type of methodology was the cross-comparison qualitative research, which was conducted to answer the following research questions;

- What is an Essential Medicine List and why do countries need it?
- What are the characteristics of an effective EML Programme?
- To what extent have other countries succeeded in their implementation of an EML?

The information was extracted from several publications, some were official government resources and others were published online at the WHO library and other reputable scientific journals.

3.16.1 Countries Investigated

The choices for the first part of the comparison were conducted at an international level, to gain an international perspective and be able to compare the implementation of EML in a variable international setting.

The countries chosen were different in their geographical location and different standards of living.

3.17 Language of the Data

The data presented in the official resources was in several languages, the main language was English but some countries used French and others used Arabic.

Translations were required, google translate was used to translate French into English. The Arabic references were translated by the author, because it's the researcher's mother language.

3.18 Summary

The Methodology Chapter has drafted the research work conducted in this study, the Chapter started with a brief introduction to describe the work in the Chapter. It discussed the philosophy of the research methodology, the paradigm used, and the type of methods and all the required justification for approaching the research questions with this type of mixed method approach. The use of the mixed method was argued and it was found that due to the nature of this research work, using a mixed method approach is the best choice in order not to miss out on data.

Methodology aspects such as confidentiality, ethics, validity, reproducibility, sampling, data analysing techniques, etc. were all described and discussed in detail. The limitations and the challenges faced in this study were all mentioned and discussed fully.

Chapter four

Findings and Analysis

4.1 Introduction

This chapter presents the outcome of the research. The sole purpose of carrying out the research work was to be able to answer the research questions, and since the framework of the research was divided into four stages the findings were also divided into four, each section is equivalent to a specific stage of the conceptual framework.

The first section of this chapter is related to the World Health Organization Model List of Essential Medicine. It will explore the concept and the objective of the list and it will try to find out if the WHO EML succeeded in fulfilling its purpose or not.

The EML will be examined in terms of the evolvement of the definition from the beginning until its current form. There is a description of the timeline of the WHO EML, then all the related statistics, and an attempt to provide evidence as to whether the list would be suitable for wealthy countries.

The second part is concerned with the 5 international countries EML study, it will give a description of each countries' journey in the process of implementing EML, all the attempts the countries tried to reach the current form of the EML and the difficulties each country faced during that process.

At the third stage, there is a comparison between 12 Arabic national EML; this might help in giving an idea on how Kuwait EML can be presented.

The final section of this chapter is related to Kuwait and the health situation in the State of Kuwait Public Sector. In this part it will be demonstrating the output of the questionnaires and the interviews conducted. It will include the charts created with SPSS to analyze the questionnaires and the interviews findings.

4.1.1 The World Health Organisation Model List of Essential Medicines

The World Health Organization is a specialized agency of the United Nations that is concerned with international public health. It was established on 7th April 1948, headquartered in Geneva, Switzerland.

WHO has been in pursuit, of good health, and trying to invent and implement programmes and policies to help the world to a better health.

One major concern, for the less fortunate countries is access to medicine and the quality assurance of the available medicines.

Many countries with the support of the WHO, attempted several efforts and policies to enhance medicine access nationally, this started in Sri Lanka as early as 1959 (J. D. Quick *et al,* 2002), Peru had another, sort of, what is known as the Basic List of Medicines. In 1960, all the efforts of having a suitable restricted list of medicines which is suitable to the country's health needs were unsuccessful, the reason being that it lacked the appropriate support and the relevant regulations to enforce it.

The concept of the WHO Essential Drug List as it was named then, started in 1977, and has evolved since that time. Initially the list incorporated almost 208 essential medicines. There was a specialised Expert Committee that revised the list every two years. Until current time, the 19th List of Essential medicines been released in April 2015. The need for an update is very understandable because disease patterns change, health profile varies over the years and medicine technology is growing and resulting in new treatment options all the time. When the list initially started it was targeted at countries with poor sanitation and limited resources, therefore the focus of the list was to treat tropical diseases, but the current lists have evolved to include priority conditions such as; Malaria, HIV/AIDS, Tuberculosis, reproductive health and, the new life style conditions and the increasing chronic diseases such as Cancer and diabetes (WHO, 2015).

The fact that the concept lasted until current times is a great testament to its validity and effectiveness. The progress of the list will be discussed later but first, the definition of Essential Medicine List development needs to be mentioned. The Essential Medicine List can be defined as '*those that satisfy the priority of healthcare needs of the population*' (WHO 2016). The concept of the List is based on a limited number of carefully selected Essential Medicines which lead to better healthcare, better drug management and lower cost. When the WHO adopted the EML, it did not aim to make it a mandatory form to be applied in the exact contents and shape, the aim was to give a model list on which the countries could design their national EML basing their choices on

diseases profile, and standards of living. The WHO Model List of Essential Medicines is only a guide not mandatory.

The concept might seem simple but to be able to produce a well-thought list of medicines and consider them ‘Essential’ is a very delicate process and great deal of experience is required (Hans V Hogerzeil, 2004).

4.1.1.1 Essential Medicine List Adaptation

The WHO continually endorsed equitable access to basic Health services (H V Hogerzeil, 2006). Shortly after the first Model List of Essential Medicines was published in 1977, the 1978 Alma Ata declaration on health for all, endorsed the list and considered it one of the WHO’s most vital and significant public health accomplishments (H V Hogerzeil, 2006). Over thirty years later the concept still standing and remains a major achievement in medicine access in relation to the WHO work in this field.

Many countries have adopted the concept and more than 156 countries have a form of national EML (USA Department of Health, 2008). Primarily the EML was aimed to resources-constrained countries, but currently it’s been seen as a practical economical tool to middle and high income countries (WHO, 2016).

The EML not only focuses on enhancing medicine access but over the years it also demonstrated further advantages, it can aid in medicine procurement and provide a better control over the process, especially when the number of medicines needed to be procured is reasonably limited and the cost is already established. Over time, the EML has demonstrated that having a well-documented list of medicines, with known quality, will help the prescriber to better practice which will enhance patients’ trust and compliances. Rational drug use is another benefit to having an EML, the reason being that having a list of medicines that is based on a well-documented Standard Treatment Guideline will contribute to better knowledge of prescribing and the follow-up of patient treatments would be satisfactory and organised.

The list has been adopted by many international organisations and they base their supply on the WHO Model EML, such organisations include, Doctors

without Borders (Médecins Sans Frontières), as well as NGOs, UNCEF, UNHCR, and UNFPA (H. V. Hogerzeil. 2004).

By 2002, it has been estimated that 4 out of 5 countries, of the WHO member countries, have EML, some even took it further and came up with more regional Lists that have fewer medicines suitable to each region's health needs (J. Quick *et al*, 2002).

In 2007, the world health sector, in general, and the WHO in particular, had noticed that children are more sensitive to some types of medications and require specific attention, for this reason the WHO published the first WHO Model EML for Children (EMLc) (WHO EMLc, 2007).

4.1.1.2 The Essential Medicines Concept utilisation by Middle to High income countries

Middle to high income countries face new challenges as life progresses and more advanced pharmaceuticals are being produced. Costs of medicine are escalating and need careful deliberation otherwise countries will be faced with a very serious uncontrollable medicine situation. from the literature review it has been established by Hans V Hogerzeil (2006), that the reason behind such inflation in medicine, is due to the current advances in pharmaceutical technologies that resulted in a reduced child mortality number, a larger aging population, and the new, less active life, resulted in the appearance of more chronic diseases such as diabetes and cardiac problems. All the previously mentioned, would result in an increased demand for medicines and subsequently it will intensify the medicine budget. Hogerzeil further explains that in the USA the Pharmaceutical budget increased by 18% in 1999, 16% in 2000, and 17% in 2001. Another major problem facing the higher income countries is the high cost of new medicines that lacked the suitable scientific background to support its quality and efficacy (H V Hogerzeil, 2004).

The following table summarises the number of medicines added or deleted each time the EML gets reviewed. The process of adding and deleting medicines follows very careful deliberation and careful decision making by qualified experts.

Table 4.1: The additions and deletions of Essential Medicines on EML from 1979 until 2011

	1979	1983	1985	1988	1990	2000	2003	2004	2006	2007	2009	2011
Master EML (core & Comp.)	235	243	263	280	293	322	331	319 (2005)	----	337	352	358
Addition	45	20	21	21	15	14	12	4	9	22	16	27
Deletion	17	13	8	13	11	6	12	(2005) 17	(2005) 17	3	4	21

Table source: WHO Essential Medicine List

The changes can happen for many reasons; the addition of new medicine could happen simply because there is more data available for its quality and efficacy, at the time of the EML Expert Committee, the added medicine safety profile is better documented and better proven. Another reason could be the availability of better evidence of the cost-effectiveness ratio (Murray Aitken, 2015). On the other hand and according to Murray Aitken (2015), the deletion of medicines from the list can occur due to lack of its essentiality, because there are better choices available at the time of making the decision. Medicines get deleted due to post market evidence of their side effects and adverse drug reactions; a major medicine deletion is due to the availability of a safer and more cost-effective medicine.

The WHO Model List of Essential Medicines is divided into Core Medicines and Complementary medicines. The WHO defines the Core Medicines as '*efficacious, safe, and cost-effective medicines for priority conditions' (*WHO, 2013).

Core medicines can be further explained as the minimum number of medicines that can relatively cover the health needs of a population. On the other hand the complementary medicines are medicines that treat a priority of diseases but require specific health technology to be given or administered. Such technologies could be specialised diagnostic or monitoring facilities and/or specialist medical care and/or specialist training may be needed; complementary medicines can be classified as such because of their cost *(*WHO, 2013).

The concept of an EML is trying to keep up with the medical advances and the WHO is always trying to come up with various options to enhance health and medicine access all over the world, but that is not enough when the concepts are not being followed accurately. Some countries adopt the EML, but never base their prescribing and procurements on it, this can lead to total failure to the concept. Other countries didn't update the list for over 5 years, in such cases the list is dated and fails in fulfilling its objectives. The WHO states that 95% of developing countries has a form of EML, but only 86% has been updated in the past 5 years (WHO. 2008). The other issue with having an EML is the availability of the essential medicines, a survey conducted by the WHO in 2008 including 27 developing countries, states that only 34.9% of the essential medicines were available at the public sector (WHO, 2009).

This is another mismanagement of the concept, because its main objective is to enhance medicine access, and since only almost 35% of Essential Medicines are available then the concept is not performing efficiently or it is not the correct method to improve medicine availability.

The WHO suggested the reason for this situation is the lack of funds, which is a long standing problem, other reasons could be more technical; the personal in-charge not managing the resources efficiently, inaccurate and bad procurement practice, failed distribution practice. The results, according to the study that is conducted by the WHO, is that the patient will resort to the private sector for medicine supply and pay out of their own pocket, these funds might not be available to some patients.

4.1.1.3 Summary

The Concept of an EML is based on having a limited number of carefully selected Essential Medicines, the concept focuses on improving the health services from various angles, it provides better drug usage and control, and it is proposed that if the EML concept utilised efficiently it will lead to cost reduction.

The WHO define the EML as '*those that satisfies the priority health care needs of the population"* (WHO. 2016) therefore, disease burdens need to be identified clearly, the quality of medicines needs to be rigorously assured,

otherwise the EML fails to accomplish its objectives and it would be a useless attempt to enhance the health of the population and a big waste of funds, staff time and efforts.

It is considered important to follow a very transparent approach to medicine selection and the medicines on the list should comply with the local Standard Treatment Guidelines, otherwise it would not generally be possible to choose medicines which will fit with the local health needs. In making the medicines selection there should be a consideration of the safety aspects associated with the medicines which were chosen, together with the efficacy and evidence supporting the cost-effectiveness. At this point it needs to be fully acknowledged that just because a medicine is inexpensive it doesn't necessary make it suitable for a certain application and any other factors should be, also considered.

Once the list is chosen and published, it is normally not introduced spontaneously, as suitable regulations are required to be put in place to enforce adherence. However, procurement of the medicine is likely to be more effective if it were found in an EML. Continuity and sustainability are also important factors which can be maintained if there are requirement and it's proposed that they might be ensured by regular revisions and updates at suitable intervals, the WHO suggest revision every two years, but this is not an obligatory.

The concept of a list has lasted close to 40 years, it's been adopted by a large number of countries with various levels of income. Many international none-profitable organisations base their selection of medicines, for donations and in case of disasters, on the WHO Model list of Essential medicines, such organisations are; World Bank, GFATM, Unicef, and UNFPA. All the previous can be considered as a demonstration of the success of the list in its objectives at some level.

Once a healthcare setting adopts the list in its typical form, and adapts it to the local health needs and practice transparency in the selection of medicines, the EML might have a type of improvement to the quality of services, and might have a positive effect on budget and fund control. A testament by the Medicines Sans Frontiers, stated that the '*the first List of Essential medicines*

was a major breakthrough in the history of medicines, pharmacy and public health'. This can be right if the list adopted in a suitable manner and altered appropriately to fit a certain country healthcare situation.

4.2 EML – International Case Studies: what has worked and what has not worked?

A comparative and evaluation case study was conducted on the process of implementing and establishing National Medicine Policy (NMP) and National Essential Medicine Lists in 5 countries with different levels of income and wealth.

Comparative research methods were used to identify, analyse and explain similarities and differences across the countries' health situation. The comparative approach has always been used by researchers '*to explain and to develop a classification of social phenomena and to establish whether a shared phenomenon can be explained by the same causes*' (Linda Hantrais 1995).

For the purpose of this study, an attempt has been made to compare 5 countries' NMP and EML, in terms of its timeline to implement it, the aims and objectives each country set when setting up the policy and the outcome of such a journey. Cross-country comparison of healthcare systems and policies is not a distinct method in the social sciences, but a diverse field that faces a distinctive set of challenges because it focuses on comparing 'large macro-social units' (Ragin 1987; 5).

This type of study has some concerns; several factors are required to be considered when conducting the comparison, such as; cultural factors, income level, political stabilities, and demography.

Another important point was required to be considered and carefully monitored and was the fact that awareness needs to be present at all times, in interpreting the outcome, it is important not to allow a country own cultural interferences to be included and to avoid bias when discussing the results (L. Hantrais.1995).

The study were conducted for 5 countries with operational National Essential Medicine Lists, it aimed to gather information about the countries

included in the study, in terms of demography, political situation, income level, health situation and past and present health policies. The study attempts to identify the process of implementing national EML carried out by each country included in the study, it is believed that by conducting this research it might help in categorising the obstacles faced by each country when the EML concept was launched, and once these issues are clearly identified it might be useful to detect the approaches used by each country to overcome all hindrances and challenges.

The comparative study was based on the information published by each country and by the work of previous researchers. In order to gain an insight to this, a literature review was conducted to cover all aspects of this study.

Going through the available literature, it became clear that there are a number of challenges faced by the countries undergoing the study. In order not to drift away from the topic, the research was directed towards health policy and National EML matters only when away from the different political challenges and economic problems many countries had confronted or still in the process of dealing with it, such political and economic challenges might have a direct or indirect impact on other aspects of these countries' stabilities, the research gathered data from as early as the forties.

Safety, affordability and the effectiveness of medicines might seem like common sense, but in reality that is not the case. It is the goal and main concern of all health services of all countries but the process of ensuring this goal is not easily attainable.

Many factors hinder the process of health innovation that ensures rational drug use and proper excess of quality assured medicines. One of the main difficulties is that the main decision makers, in health services, support their own interest rather than the interest of the majority of the population (P K Sarkar, 2004). For this reason many countries have not reached a suitable drug policy and a functioning national EML that satisfies all and ensures adequate, quality medicine access (S. Nordberg et al 1995).

Despite government efforts to ensure a suitable level of medicines access, the problem remained an issue, many suggestions have been presented by governments to overcome the problems, but not all are very successful and many have not reached the light of day and are never executed (Hoebert et al. 2013). There are several factors influencing medicine access, according to Hoebert *et al* (2013), Morbidity patterns have changed, medicine from private sectors became the new source of medicine access, changes in healthcare policies, different health insurance regulations, in addition to all the mentioned previously. There is also, another major influencer in medicines access which is the new trends and the several diverse international and national trade arrangements, the trade agreement would direct the local production of medicines to export rather than utilising it nationally and enhance medicines access (Ictsd.org. 2016). All these factors might be present independently or in combination, but the result would affect the medicine situation in each country and might obstruct patients' access to it.

The WHO's main mission is '*to help save lives and improve health by closing the huge gap between the potential that essential drugs have to offer and the reality that for millions of people-particularly the poor and disadvantaged- medicines are unavailable, unaffordable, unsafely used'* and this is the foundation of the mission of the National Medicines Policy and Essential Medicines List.

The major components for any NMP includes National Essential Medicines List, National Drug Formularies and Clinical Guidelines, together they are the foundation for fulfilling the national health target in any country, a national medicine policy wouldn't be considered as such without the three major components (WHO, 2016).

According to the WHO works, it's been established that having a National Medicine Policy (NMP) based on Essential Medicine List helps to pave the road to better health; NMP/EML identify the footsteps that need to be followed in order for the NHP objectives to take place. The WHO estimates that a time frame for NMP to be effective and operational is a 10-year period (WHO. 2003)

Since 1970, experience and time have shown that having a well-established and monitored medicine policy is very advantageous. Based on the strong health position and the work of the WHO, it's only natural that WHO takes the leading role in the process of implementing and setting the guidelines for health policies. This is the case in the majority of the countries that started medicine policies to improve services and general health (S. Nordberg et al 1995). The WHO however only merely set guidelines for countries to refer to when implementing their own policy; the health policy and the choices of medicines on the National Essential Medicine List, differ in accordance with each country's situation, and many factors needs to be considered when planning the list.

When setting the framework of any policy, it's important to consider cultural and historical factors; the country's ability to reregulate and enhance quality assurance, the country's financial capabilities, the pharmaceutical situation and the strength of government enforcement of regulations; since these factors tend to change with time, updates and reviews should be carried out at reasonable time intervals (Hogerzeil, 2004).

Currently and since the seventies, a vast literature has become available to countries to carry own policy that would enhance medicine excess and improve medicine quality. Unfortunately not many countries have taken up this facility and the ones who did, have been faced with a number of challenges that requires a close inspection and deliberation to gain an understanding of other countries' experiences with medicine policies (S. Nordberg, 1995:1).

The following figure demonstrates countries with an NMP divided according to income level. The figure is sourced from WHO level 1 survey, as appeared in the World Medicine Situation Report 2004 and the global overview of pharmaceutical sector country profiles (2011).

The bar-chart demonstrates that low income countries have more NMP/EML in place than high income countries and the percentage has increased over the years. It makes sense in a way that low income countries are always trying to find means to reduce expenditure and reduce strains on budgets.

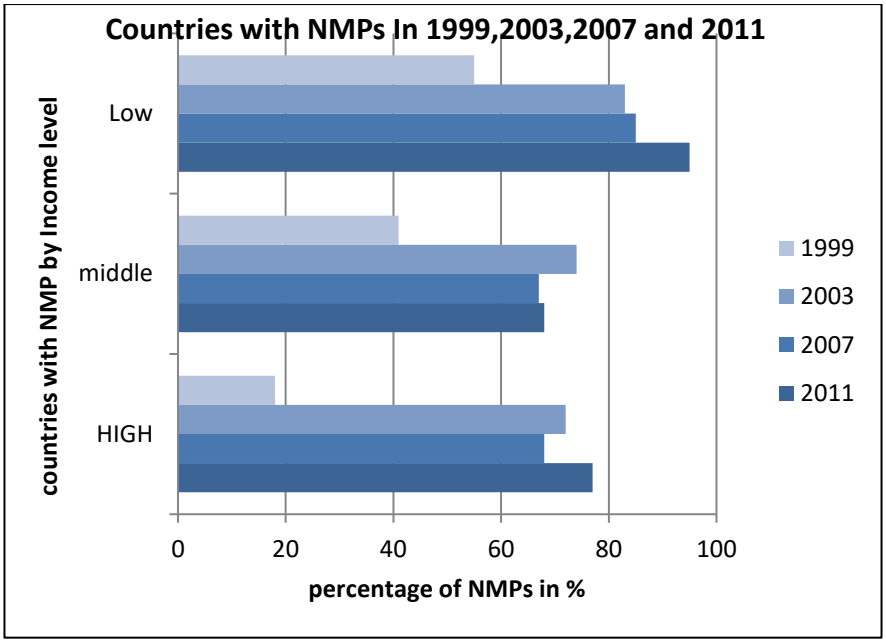


Figure 4.1: Trends in the formulation of national medicines policies (NMP/EML), by countries' level of income, 1999, 2003, 2007 and 2011.

Source: WHO level 1 survey (as appeared in the World Medicines Situation Report 2004), and the global overview of pharmaceutical sector country profiles (2011). Percentages are based on number of countries surveyed by WHO.

Laing *et al*, suggests that low and mid income countries adopted Essential Medicines with the aim to improve all aspects of the pharmaceutical sector, such as; selection, procurement, distribution and rational drug use (Laing *et al*, 2001). It's an understandable to believe that having a small number of well documented and assured quality medicines can contribute in cost reduction during procurement and provide a type of a more focused medicines management.

Walley suggests that high income countries do not have a set and unified NMP/EML (Wally *et al*, 2000). That being said, most high income countries have policies directed at pricing or purchasing (Rietveld, Haaijer-Ruskamp. 2002).

The following map demonstrates the distribution of NMP/EML around the world. The figures were collected in 1999; it shows that 44% of the world have published NMP/EML within the past 10 years, where only 3% had NMP/EML older than 10 years. It also shows that almost 24% have a draft of NMP/EML

but it is not fully operational yet and around 29% have no official documents (WHO, 2004).

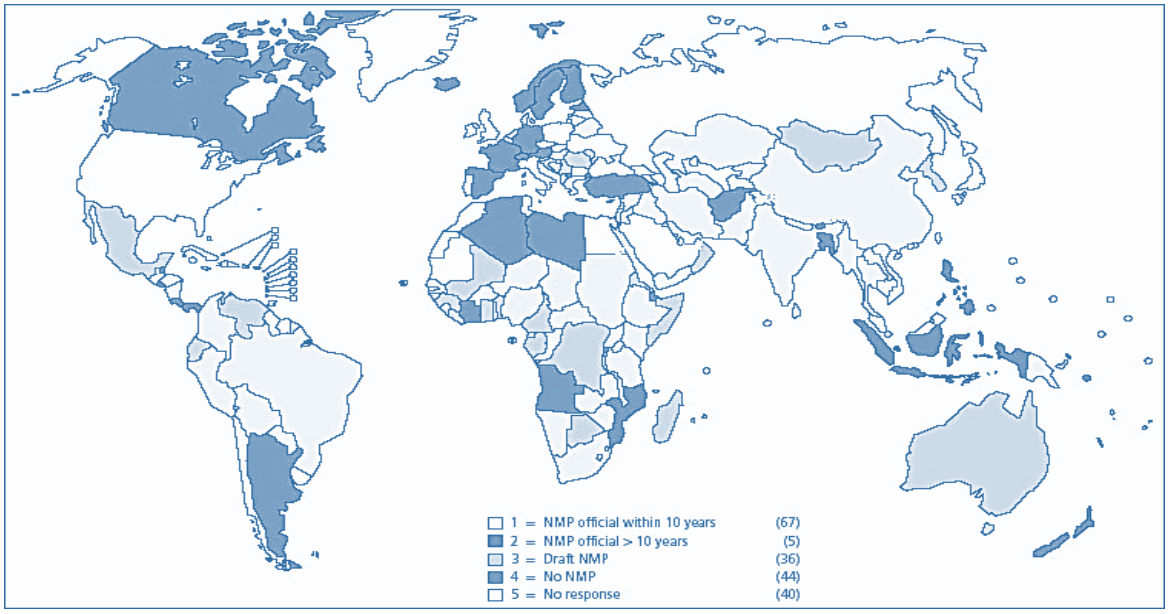


Figure 4.2: Formulation of national medicines policies worldwide, 1999
Source: WHO Website, accessible through
http://apps.who.int/medicinedocs/en/d/Js6160e/8.html

Table 4.2: cross comparing the existence of NMP/EML with the level of incomes	
Years of NMP/EML	**No of Countries**
NMP/EML within 10 years	67
Official NMP/EML more than 10 years	5
Draft NMP/EML	36
No NMP/EML	44
No response to survey	40
Source: the data adopted from the WHO website, World Drug Situation Survey (1999), accessible through http://apps.who.int/medicinedocs/en/d/Js6160e/8.html	

When cross comparing the existence of NMP/EML with the level of incomes in countries, there were clear indications that countries with less income try to adopt means to control medicine budget in the form of having n EML. The following table shows this outcome, the source of this table is WHO, World Drug Situation Survey (1999).

Table 4.3: Formulation of national medicines policies in low-, middle- and high-income countries in 1999.							
Status of NMP/EML document	**Low-income**		**Middle-income**		**High-Income**		**Total**
	No of Countries	% No of Countries	No of Countries	% No of Countries	No of Countries	% No of Countries	
Official document within 10 years	35	56	29	41	3	17	67
Official document > 10 years	4	6	1	1	0	0	5
Draft document	18	29	17	24	1	6	36
No document	6	9	24	34	14	77	44
Total	63	100	71	100	18	100	152
Source: the data adopted from the WHO website, World Drug Situation Survey (1999), accessible through http://apps.who.int/medicinedocs/en/d/Js6160e/8.html							

The work of the WHO states that, only in recent years, have high income countries turned towards having published official NMP/EML documents, but many high-income countries have a very well-regulated pharmaceutical system without the written document (WHO: The World Medicine Situation. 2004).

The following figure demonstrates how the trend of having NMP/EML grew over the years in all levels of incomes, but there is greater growth in the recent years in high income countries.

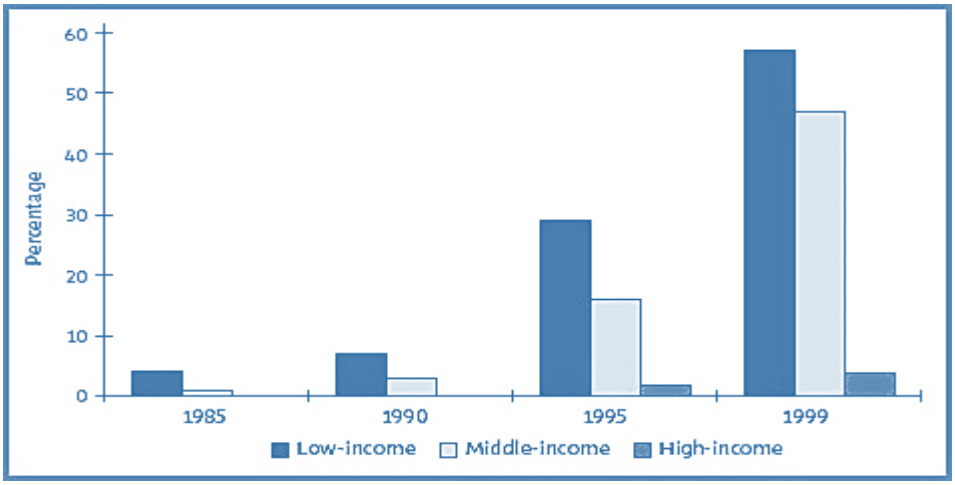


Figure 4.3: Trends in the formulation of national medicines policies, by countries' level of income, 1985-1999. Source: World Drug Situation Survey (1999)

The NMP/EML setting is however country-specific and cannot copy other countries' process, but it's important to gain experience from past lessons. The WHO made commendable efforts in setting guidelines on National Medicine Policies; they are clearly presented in publications outlining the process of starting an individual policy. The guideline is not specific to each country and requires adjustments in accordance with each country situation. The WHO suggests that it's very difficult to ensure a NMP/EML is effective if the country is going through strains such as; financial and economical, it's particularly tough in countries where the majority of the pharmaceutical market is private. The result of such situations is that the prices are very difficult to regulate and control (WHO, 2004).

Countries described later, are chosen for several factors, but mainly there was focus on chosen countries with different levels of wealth. It's only fair to research and carefully study different countries from diverse levels of living and different demography. For this reason 5 countries have been chosen; Norway was chosen because it's an example of a high income country with an almost impeccable Health System, they are considered a pioneer in health system planning (Ian McAuley, 2014). Sri Lanka and Bangladesh are low income countries with a large percentage of their health budget based on donations (Ananda Jayasinghe, 2004). Australia is a country with a very diverse population due to immigration; it might be worthwhile to view their experience in dealing with very different authenticities (Australian Government, 2011). India, considered one of the early third world countries, tried to implement and adopt a National Medicine Policy, since 1970s the attempt has been made but that doesn't indicate in anyway if the efforts were successful (Bidwai P. 1995).

4.2.1 Norway's Experience with National Medicine Policy and EML

The Health Services in Norway are free to anyone under the age of 16 and free for pregnant ladies (My Little Norway. 2009). Hospitals are funded by the public by taxes, but adults get an exemption card to allow them free visitations to the Norwegian public hospitals, this exemption card is paid for yearly (Norway Ministry of Finance, 2012).

Norway has the highest expenditure in health in the world (Britnell, Mark. 2015). With that thought Norwegians are still required to pay for extra specialised care, such as; physiotherapy, any extra materials and medical equipment (My Little Norway. 2009).

In Norway, almost all the major pharmaceutical companies and manufacturers are presented, but only a few of them are in production and of manufacturing status (Norwegian Medicine Agency. 2016).

In terms of a medicine list, Norway always had the need for a specific medicine clause. The result was an almost constant list of medicine for the past 20 years; Norway health authorities believe that it is important to prevent individuals from unnecessary medicines.

Table 4.4: shows the trends in which the medicine in Norway has changed since 1974 until 1992

Year	**1974**	**1977**	**1985**	**1992**
Number of Medicines	1,903	1,889	2,080	2,244

Source: created by author based on data from Norwegian Medicine Agency. 2016

The above table shows the trends in which the medicine in Norway has changed since 1974 until 1992. (Marit Andrew *et al*. 1995) it's important to note at this stage that Norway has the highest standard of living in the world; a health policy came into action from 1994-1997 to ensure access and quality of medicine and other health services. The introduction of the policy was welcomed and well received by all political parties the debate was in the form of the process of implementing it and how realistic is this approach (Marit Andrew et al. 1995).

In the early eighties, Norway realised the importance of preventive medicine rather than curative and focused their efforts to establish a more preventive strategy (Siem, H. 1986).

When Norway developed the National Drug Policy, they had areas that needed to have special consideration and focus; the main area was to evaluate the health situation in general, together with a specific consideration to the healthcare system. Another area of concern is the health professional level of

education and experiences; they focused on health insurance and social security; Norway has always thought that maintaining high standards in health research is very important. The drug industry is very important and requires careful monitoring; the process of drug distribution has to be efficient and appropriate. Another two areas that were considered were the control over the medicines available and assurance of rational drug use and good attention must be paid to the international drug policies.

When the Norwegian Healthcare Services planned their Medicine List, they aimed to include and select medicines with high safety margins and medicines with established efficacy. Medicine accessibility was an important consideration together with promoting rational drug use. The chosen medicines should comply with the national health burdens, diseases profile and country needs.

Norway made early attempts in enhancing medicine quality, years before the modern forms of international ethical regulations. The first act of Drugs and Poisons came as early as 1928, medicine had to be approved, and advertisements need to comply with government regulations. It is a positive step towards quality assurance, but during that period the available data was very limited and the quality of medicines couldn't be assured fully.

The concept of Essential Medicines has been strong in Norway and been enforced by the national health services in Norway; the focus of the Essential Medicines was not for cost reduction only, but also to illuminate irrational drug use. The following explains how the director of Health Services in Norway was considered the initiator in EML concept foundation.

4.2.1.1 Essential Medicine Concept in Norway

The Director of Health Services in Norway from 1938 until 1972, had clear insight to the issue of irrational drug use, he even wrote a book to explain its concept and view. His successor, Torbjorn Mark, agreed and continued in the same path, he was one of the main players in the foundation and introduction of WHO's Action Program on Essential Drugs (DAP). He was an

actual builder of the initial Essential Medicine List and Pharmaceutical Policy and was the director of the Pharmaceutical Services from 1965 until 1991.

In 1977, Professor Lunde, Head of Dept. of Pharmaceutics, drafted the first Essential Drug List.

Like many, industrialised and wealthy countries, Norway did not have in place an actual document of a National Health Policy nor an actual written form of an Essential Medicine List. In 1987, but a paper was introduced to the parliament with a section related to developments in the pharmaceutical sector. Included in the document is the expectation from the pharmaceutical sector in terms of providing safe and effective accessible medicines to all Norwegian communities. The section ensured; rational drug use, and health professional education. The focus of the proposed policy is the foundation of a pharmaceutical regulation body, and to control all aspects related to health and medicine use.

In 1930, the Quality Control Department was launched, then in 1948 drug standardisation was introduced and in 1974, the Norwegian Medicine Control Authority (NMCA) was set up. The NMCA had a medicine selection criteria, it was closely similar to that which had been suggested by the WHO; the following are the main requirements for any drug to be included in the List of Medicines in Norway;

- The Norwegian Health services based medicine selection on the medicines list and on sound scientific research and strong scientific evidence.
- Important consideration is given to the efficacy/toxicity ratio against disease severity and how effective a drug is in the healing process.
- Norwegian Pharmaceutical services preferred to select new medicines that are supported with solid scientific evidence of quality.
- It’s common practice in most health services to avoid fixed-drug combination unless it is proven to be superior to each combination individually taken.

- The clause related to the need, must be considered every time a choice is to be made.
- There should only be a specific and limited number of medicines.
- All medicines are reviewed after a 5 year approval period.
- There are specific restriction as to who can use a medicine and who can prescribe it, such as Hospitals and prescribers.

In 1994, Norway was concerned that the number of medicines on the list might increase, therefore they introduced a directive that the medicines should not only be scientifically justified, but they should be needed. It's common sense to include only relevant medicines to the health needs of the nation, otherwise, there is a waste of resources and the reasons for that choice are not critically chosen.

A positive point found in the process of registering new medicines was that the choice is not indefinite and requires regular updating and review. In addition, leading medical experts are routinely consulted. Involving professionals from different clinical backgrounds which has helped to gain support for the pharmaceutical and health policy.

On the other hand, the challenge was to preserve the concept of Essential Medicines against the pressure of free trade, as with any new policy, and in this case, it relates to medicines, the industry in Norway accused the regulators who set up the list of being restricted. However at the same time the regulators were warning of the dangers of deregulating the NDP.

The Norwegian experience with medicine selection and health policy is however commendable, although Norway has a very high income, that did not mean that the medicine list should go uncontrolled. They focused tremendously on the clause related to need, which indicated, a medicine would only be included if it is really needed and supported by evidence of safety and efficacy.

In comparison moving to a country with limited resources and a less developed health programme, Sri-Lanka, which has suffered from various political conflicts, financial and social challenges. The next segments will

demonstrate how this been handled and how Sri-Lanka tried to make use of the limited resources they have.

4.2.2 Sri-Lanka National Drug Policy and Essential Medicine List Experience

Sri-Lanka became independent in 1948; they tried to provide free access to education and healthcare to all the population. Although an NMP/EML was not in place at that time, there were a number of laws, reports and recommendations to control the healthcare position of the country.

In 1962, the National Formulary Committee was launched as a result of the work of Professor Senaka Bibile. The committee was able to reduce the number of medicines to 2100 medicines, but unfortunately many conflict and political events occurred resulting in an ending of Professor Bibile's work and the developments to control of pharmaceuticals were lost. However in the last 5 years the work started by Prof Bibile has started again and is close to being completed today. The reasons for this were; the powerful external pharmaceutical industry and the vast number of generics instead of brand names which were being imported, particularly from India. Later in the eighties and nineties a stronger government was established and imposed a more powerful control over the generic industry and a health reform took place. Examples of this reform were seen as a more restricted medicine registration procedure, introduction of the concept of the need for the medicine and strong proof and unbiased medicine information. Over the next 15 year there were a large number of reforms and regulation changes in Sri-Lanka.

The following timeline demonstrates this, starting in the fifties, where the government, due to lack of proper experienced health decision makers, adopted specific international pharmacopoeias as a reference to approve medicines without any regards to how suitable the medicine was to the needs of Sri Lanka, at the time However although the decision was justified, it gave the local healthcare system no choice over what is suitable and what is not. As a result, in 1957, concerns arose over the loss of control and as a result a Formulary Committee was launched to set out further guidelines and provide a means of control over the stocking of medicines. The list of medicines on the formulary

were only related to the public sector, as the private sector continued to import all kinds of medicines that are not included in the public sector lists (K. Weerasuriya 1995).

In the sixties, the economic situation of Sri Lanka wasn't in a great position, and for this reason, the government needed to demonstrate and enforce control over medicines to control the budget. For this reason the Ministry of Health introduced the National Formulary Committee (NFC) to act as a regulatory body and review the 4000 available medicines and over 6000 pharmaceutical dosage forms and reduced them to 2100 and 3000 dosage form. The government also gave the NFC the power to approve medicines before they were brought into the country. However this kind of practice was not common in countries at the time. The two major criterion Sri Lanka focused on when importing a medicine was affordability and usefulness.

In 1977 however a new government came into power, which had the approach of encouraging again the private sector and free trade in pharmaceuticals, (Lall, S., and Bibile, S., 1977). The business people with high resources saw this as a chance to redevelop the pharmaceutical market and import more expensive drugs. They however faced resistance from the State Pharmaceuticals Corporation (SPC) under the support of the Ministry of Industry, and SPC took control of imports in a phased manner, with minimum disruption to the supply of pharmaceuticals (Bibile, S. 1977). Further to this work the government introduced the Cosmetics, Devices and Drugs Act (Gazette of the Democratic Socialist Republic of Sri Lanka. 1985).

4.2.2.1 Essential Medicine List of Sri Lanka

In 1985, the first meeting was held to introduce the Essential List concept, attendees of this meeting were officials from the Ministry of Health, a few academics and a member of the Medical Association, who was an advocate of the pharmaceutical industry. In 1988. As a result of this meeting the EDL was revised (Department of Health. 1988). The pharmaceutical industry however tried to oppose the EML but when asked to provide a written statement to support the opposition, they failed to do so.

From these meetings both the private and public sectors of health have similarities in their prescribing approaches, and the top 10 medicines at that time were prescribed from the Sri Lanka EML which had been developed (Weerasuriya, 1989).

As can be seen from the information above Sri-Lanka Health Services have gone through many years of turmoil up to the nineties and they were faced with a strong pharmaceutical and political opposition. But they managed to stand against such challenges and the EML was beginning to be used in an efficient manner. Although it is suggested that the changes that took place in Sri-Lanka, were more economically inspired rather than health or scientific based.

But the difficulties in Sri Lanka were not fully resolved and a political-religious issue was developing which was to last about 15 years. This was through the Civil War between the Sinhalese – Tamil religious groups. This led to a major disruption in keeping the pharmaceutical developments in place. However there has been peace in Sri Lanka in recent years and the Pharmaceutical Regulation and the introduction of a National Drug Policy in the last year has re-energised the developments. It can be said however that the Sri-Lanka experience is country related and may not be appropriate if it were to be applied to other countries, but there are some similarities with Kuwait in terms of the periods of conflict and movement on an EML. It is therefore considered important to take lessons from their experiences and make use of the knowledge gained from the challenges that have been faced and the method by which the country overcame them.

4.2.3 Bangladesh National Medicine Policy Experience and Essential Medicine List

Bangladesh gained its independence in 1971; it has a poor, undiversified economy, with increasing population and lack of infrastructure. The infant mortality rate was high; in 1972 it was 140 per 1,000 live births. The health facilities were inappropriate, unmaintained, access to Essential Medicine was not in place and inefficient quality control system and counterfeit drugs were in circulation. The first basic Medicines Act was in place in 1940 and it was not

reviewed, and was therefore inadequate. It was not until 1975 when a new government came out with a new Act in 1975, that there was major movement again, but even with the new act there was no control over medicine quality.

In 1982, the Bangladesh Council of Ministers approved the proposals for a National Drug Policy, the interesting aspect of the work of the Expert Committee was that the work was done promptly and didn't develop over an extended time. The Expert Committee worked out the policy, based on 16 criteria, in 15 days. Later in the same year it became a law. However the opposition, as expected, came from the pharmaceutical industry which was however not particularly developed and regulated at that time. But that did not affect the decision and the Policy and Report was introduced. However there has been little progress from the 1980's and hasn't changed much in the following 13 years. It however had a positive impact on the healthcare in general, in terms of dropping prices, adherence to the Essential Medicine List in procurement and prescribing, increased quality of production, and health professional awareness of the medicines has increased positively (Z. Chowdhury 1995).

The Committee which discussed and formulated the Report and Policy was composed of Academics, Regulators, and Health activists, they were 8 in total. The Committee members were chosen from areas to exclude bias, for this reason, no members were chosen who had any relation with the pharmaceutical industry. The members were knowledgeable of the past experiences of neighboring countries such as; India and Sri Lanka; and it was the first and last committee in Bangladesh that didn't include a civil servant or a military bureaucracy.

The Committee decided to follow the guidelines generally set by the WHO, in the selection of medicines. The committee made decisions using the scientific literature available at that current time and to only make deletions on medicines after a unanimous decision. The report the committee submitted included the rationale behind the decisions made and an action plan. The decision was also made to make the written document in simple, clear wording, avoiding difficult scientific words in order to make it understandable by all

readers. Because confidentiality was very vital at this point, no secretary was used and all members were vowed to strict secrecy until the report became public. The concealment approach proved to be useful, as the work of the Committee was achieved. The Committee managed to ban 1,742 medicines that they found inappropriate for several reasons. The recommendations for the drugs to be in the list were as follow:

- Establish a basic list of 150 essential drugs and a supplementary list of 100 specialized drugs. The total number of drugs on the list was to be available in all tertiary healthcare facilities; only 12 were available to be prescribed for village workers and 45 medicines were available for prescribing in primary healthcare facilities.
- The 45 medicines available for prescribing in primary healthcare needed to be addressed by generic names only.
- National Formulary needed to be prepare and publish a by 1983.
- Eliminate product patents and limit the use of process patents.
- Revise the 1940 Drugs Act to include:
  - a registration system for Ayurvedic, Unani and homeopathic medicines;
  - enforcement of good manufacturing practices (GMP), including adequate quality control;
  - control of labeling and advertising;
  - price control;
  - prescription control of toxic/poisonous and habit-forming drugs;
  - establishment of special drug courts and heavy penalties;- regulation of technology transfer and licensing agreements with foreign collaborators;
  - Restriction of ownership of retail pharmacies to professional pharmacists only.
- Set up a National Drug Control Laboratory by 1985
- Prevent TNCs from manufacturing simple products like common analgesics, vitamins and antacids.

- Establish registered retail pharmacies, under the supervision of qualified pharmacists, at every government hospital.
- Strengthen Drug Administration by training all 5 health administrators to act as drug inspectors.

The National Drug Policy also came into action to control all aspects of manufacturing, procurements, distribution, medicine use and quality control.

It is possible at this point to ask the question with respect to the 'small number of medicines' as there were only 100 medicines on the list which can be considered as very limited. The rationale according to the committee is that, they had conducted a study among practitioners and they found that the prescribers used only a total of 50 to a maximum of 100 types of medicines (WHO. 1979). As a result, almost all the pharmaceutical manufacturing companies were affected by the committee decisions; and there were 166 at the time.

There were also other problems the Committee and the Ministry of Health had to face. These included the fact that Bangladesh depended on the donations of several countries, and as a result the NMP/EML was faced with rejection by a number of countries. In the case of the USA their objection in supporting the List was because they did not seek their approval on the decision-making process as it would conflict with the American interest in the country. The German and the British also had similar oppositions to Bangladeshi attempts to control the medicine situation in the country and Bangladeshi efforts to enhance medicine access to the population (Z. *Chowdhury*, 1995).

The opposition did not come only from the Western industrialised countries but also from small companies in Bangladesh. With this opposition a public hearing was made by officials in the Bangladeshi government and they reacted by stating that the oppositions are merely protecting their own financial and commercial interests. As a result the Government went ahead with the document of NMP/EML and it was made public in 1982. But the NMP/EML, was faced with international opposition by other Governments, but against this it was also received well by human rights activists. This caused a lot of concerns and

antagonism by Transnational Corporations (TNC), fearing the other countries would follow the same path and that was true as shortly after, in 1983, India followed a similar path.

The result of the NMP/EML was evidenced however in the country and was demonstrated by increased local production from 30% of essential medicines to 80%, and prices were somewhat stabilised. This meant the drugs were more accessible to the population. But these were not the only gains, the local production increased with less dependence on import and most importantly the quality of medicines increased.

The opposition against the Bangladeshi NMP/EML however continued throughout the eighties and nineties but the support of the WHO and UNICEF gave it strength. But although the struggle to implement the NMP/EML continued, part of the policy is still operational.

4.2.4 Australian Experience

In 2010, Australia had a population of 22,3 Million. It is one of the world's most urbanised countries, with around 89% of Australians living in urban areas (WHO, 2010).

Australia's healthcare system is a complex combination of public and private sectors; 50 years ago, Australian government decided to make reforms to ensure that all the population have free access to medicines. They developed a comprehensive National Drug Policy, the policy aimed to provide a limited number of life-saving medicines to the population free of charge. They included a process of ensuring price control over medicines. This yielded a greater reduction of medicine prices than anywhere else in the word, costing almost 60% less than what they cost in the European countries. This was the case in the previous decades; the prices are now more due to pharmaceutical innovation and developments.

Price control and medicine access were not the only two criterions considered by the Australian government, another important aspect is that the quality of pharmaceuticals had to be high and effective with a high safety profile (M. Murray, 1995). Australia has faced a number of challenges when setting up

the policy, mainly because of the diversity of the demography, plus other challenges such as aging population, changes in disease pattern, advancement in medical care and, as in most communities, the high expectations of patients.

When the Australian Health Services developed the Australia Health Policy and the Essential Medicine List, they aimed to achieve the following '*to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved*' (National medicines policy 2000). The policy was designed in a way to achieve four main objectives, the objectives are as follows:

1. Access to suitable medicines related to the Australian health needs in good time, with suitable cost.
2. Medicines with proper quality, safety and efficacy.
3. Preserving suitable pharmaceutical industry.
4. Rational Drug Use (National medicines policy 2000).

The following diagram represents those four objectives best; the source of this diagram is the Commonwealth Department of Health and Ageing 2002 (Commonwealth Department of Health and Ageing. 2002).

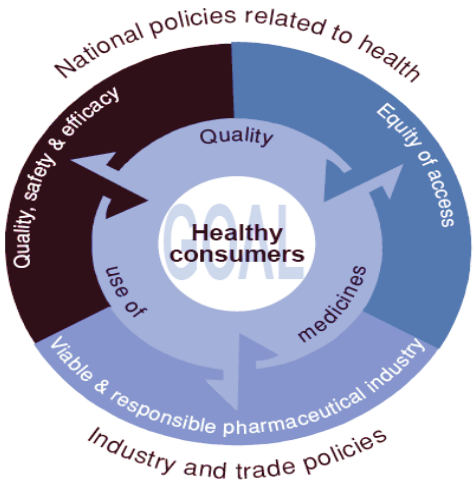


Figure 4.4: Medicine Policy major Objectives
Sourced from the WHO Document, National Medicine Policy, Chapter 4.

The diagram illustrates the major objectives considered when implementing the policy, they are very similar and can be related to all

countries, the process of ensuring adherence to the objectives and guaranteeing its implementation is key.

What Australia did was to construct a complete National Drug Policy slowly but steadily. The process started 40 years ago and it's still an on-going process (Mary Murray, 1995). According to Murry, all the objectives had been addressed except rational drug use which remained a concern, as there was evidence of overuse, wastage, underuse and misuse (Mary Murray, 1995). Thoughts were then directed towards making a separate policy for rational drug use, but that would indicate that the National Drug Policy was not strong enough, and the reason behind it according to Murry, was that there was tension between health professionals and there were economic reasons. The agreed solution was to revise the current NDP/EML and reregulate it to suit the issues and challenges faced. This has however taken a very long time to develop and demonstrates the conservative nature of Australia.

Another major concern that caused Australia to re-evaluate its NMP/EML is the fact that the demography keeps changing due to immigration from Asia and Europe.

The following is a brief description of how Australia dealt with each objective.

4.2.4.1 Access to suitable medicines related to the Australian Health needs in good time, with suitable cost

Australia came up with The Pharmaceutical Benefits Scheme (PBS), systems provide general public subsidy to make frequently used medicines more available and affordable (Raftery JP, 2008). The system started in 1950 with 139 essential medicines prescribed free of charge and now PBS subsidises 593 medicines in 1,451 formulation. A self-governing legal organisation, the Pharmaceutical Benefits Advisory Committee (PBAC), is responsible for endorsing which medicines are listed on the scheme (E.E. Roughead, no date).

4.2.4.2 Medicines with Proper Quality, Safety and Efficacy

This is the role of the Therapeutic Goods Administration, to ensure quality of circulating medicines. The Administration launched in 1958 in the form of a laboratory. Current premarket surveillances are being carried out and the Administration is responsible for drug registration and post market surveillance.

4.2.4.3 Preserving Suitable Pharmaceutical Industry

The pharmaceuticals partnership program (P3), is the current program used by the Australian Government to monitor the Pharmaceutical industry since 2004, but before that, in 1998, it used to be known as the Pharmaceutical Industry Development Program. According to Australian Pharmaceutical Manufacturing Association, production and research has evolved since the introduction of the program (Productivity Commission, 2003), (Australian Pharmaceutical Manufacturing Association, 2000).

4.2.4.4 Rational Drug Use

The WHO defines rational use of medicines as '*patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community*.' (WHO.2015). Australia detected several incidences of irrational drug use. The Australian government established The National Policy for Quality Use of Medicines in 1992; it drew a multi-level, multi-strategic systems method to accomplish rational drug use (Commonwealth Department of Health and Ageing, 2002).

Policy making needs to be based on realistic approaches and aims, that benefit the community and is for the community, it's a relationship between policy-makers, health professionals and the community. If this is not considered and consulted the policy fails its target, which is the general well-being of the community. Australia understood the concept and realised NMP is partly about medicines but is actually more about the overall well-being of the people with all the different levels of diversity (Murray, 1995). What Australia did was set up a committee for each objective to ensure its properly controlled and managed, they came up with regulations that will ensure adherence to the plan in hand,

and delayed the process of registering new medicines to not over flood the market with new drugs that have little information available to support their quality and efficacy claims.

4.2.5 India NMP/EML Experience

Since the seventies, India aimed to have a form of national medicine policy and an essential medicine list, it can actually be back dated to the early years of India independence, India can be considered as one of the first third world countries trying to set up a NMP/EML. Unfortunately the policy failed to deliver due to the fact that the objectives were not clearly set out and the aims were not very significant to the population (P. Bidwai, 1995).

Another reason for NMP/EML failure was because, the concept did not focus on Essential Medicines List and the need clause, as most countries targeted when planning the policy. A major reason for the failure to deliver is the extremely powerful pharmaceutical industry, that made the policy, basically diminishes in the eighties. Since the fifties, India's pharmaceutical industry was controlled by transnational corporations (TNCs), no price control was achievable and no proper regulation were in place; quality was unregulated, irrational drug use was common, especially because of untrained chemists and witch doctors (refer to healers, particularly in third world regions, who use traditional healing rather than contemporary medicine). India tried to control the situation by coming up with regulations to control TNC's, but TNC's managed to escape them. The Indian government came up with three things to contain the situation:

1. Set up indigenous antibiotic production lines in the government sector.
2. Intellectual property right changes, this would give chance for domestic pharmaceutical producers, it removed patency from food and health-related products and reduced patency duration for pharmaceuticals.
3. Create a system to test the quality of drugs through Indian FDA.

The timeline India went through to set up the final draft of the NMP/EML is very intensive. It started in 1946, at the evening of independence, a complete NMP/EML was prepared with a description of what the National Health Service

should be, it included what needed to be done to enhance the current services and called for structural changes (Duggal, 2001). This plan was not adopted straight away; instead the Indian government had a series of 5 year plans. The fault, which had been seen by Banerji, is that these plans focused on eliminating epidemics and not enhancing the health services in general (Banerji, 1985). Another major fault in these plans is the fact that Indian health services depended on international donations for the majority of its health funds. For this reason any plan in place was controlled by international experts who saw to their own interests and politically controlled these plans resulting in its failure (R.Duggal, 2001).

In 1959, Mudaliar Committee was setup; it concluded that more than half of the population lack access to any appropriate health facilities, trained medical staff and Quality Medicines; this need to be addressed (Mudaliar, 1961).

In 1961, a third plan was started. The outcome of this plan is that, the previous plan failed to deliver its target and the population, especially in the rural areas, lack access to basic health needs (R.Duggal, 2001). In 1969, a fourth plan started. According to Duggal this was the most poorly written, and achieved almost nothing (R.Duggal, 2001).

A number of plans followed such as the 5th Plan that came up with the Minimum Need Programme (MNP), in a way to try to control the discrimination between rural and urban areas. Then in 1973 Kartar Singh Committee followed by the 1977 committee, which focused on the health workers, for this reason this committee set up another committee called Community Health Workers Committee and in 1975 Shrivastava Committee was launched. And so on it went until finally in 1983, India's first official National Health Policy was launched and adopted by the government. The policy was planned and prepared based on the principle recommendations of the Indian constitution, which clearly state the following '*universal, comprehensive primary health care services which are relevant to the actual needs and priorities of the community at a cost which people can afford*.' (MoHFW, 1983, 3-4).

In this document, it is the first time Indian Health services are clear on the objectives of the Policy and acknowledge the main beneficiary, which are

the people. Years after the launch of NHP/EML and in 1992 an analysis was carried out to trace the progress of the policy, but the conclusion was disappointing, because according to several researchers in 1983 the general National Health Policy, which included the Essential Medicine List, was not realistic and did not meet the demands of the rural area population, therefore it did not meet its objective of being universal and comprehensive (NSS-1987, Duggal&Amin,1989, Kannan et.al.,1991, NCAER,1991, George et.al.,1992).

In 1991, India went through economic changes and a new NHP was launched, the financial crisis India was going through, left it with external debt mounting to US $70 billion. Surely this would delay reforms and improvements and obstruct the effective operation of the NMP/EML.

It seems, from the above timeline that every time India tries to do something, a major crisis or obstacles arises preventing them from achieving their goal. The reasons are not as clear as one might think, it is obviously financial, but it also has many other factors that require several exhaustive studies to point out.

4.2.6 Summary

The attempts of medicine cost-control has been the aim of many countries, regardless of the income level, the concept of Essential Medicines has been adopted by many countries, the reason is not only to control costs, but there are several reasons for it.

A major benefit to the EML is the quality assurance objective, it is believed by many countries that having a smaller number of quality medicines will ensure better control over observing them and reduce wastage.

Many other benefits have been paired with the concept of EML, such benefits are the rational drug use, enhance of health professional experience with the Essential Medicines, which will result in better patient compliances, minimisation of wastage, which is yet another form of cost reduction and promotion of good procurement practice.

The concept of Essential Medicines is very disturbing to some stakeholders, who have a number of losses if the EML gets implemented; this is mainly seen in the Pharmaceutical Industry where they strongly oppose the implementation of the concept.

The less resourceful countries had very early attempts to launch the concept of Essential Medicines, even before it was adopted by the WHO and launched officially.

The opposition was always there and economical and political crises have always halted the concept. Currently, it's more feasible to start the concept, because there is much more support from international organisations for the concept and the knowledge of medicines is easily available, health experts are more knowledgeable, even in a developing country, and more developed countries with good resources are adopting the concept.

The following section will compare the available Essential Medicine Lists for all the Arabic countries, and aims to provide an insight into the structure of the List. The Arabic countries share similar health profiles to Kuwait but they differ in their standards of living.

4.3 Arabic Countries Essential Medicine Lists

Over the past few decades, Arabic health has gone through major improvements (Kronfol NM. 2012), it's been found that between 1990 and 2010, the mortality rate in the Arab world decreased and the population has aged (Malak Makki. 2014).

Over 30 years ago the concept of an Essential Medicine List was not available, few countries had the concept in place and it was not fully organised.

The List became popular over the years and proved its benefits, this is evident because it's been adopted by over 100 countries worldwide (WHO. 2015). In April 2015, the 19th revised WHO model EML was published and up-to-date, there are 117 National Essential Medicine Lists available worldwide, in the Arabic region, around Kuwait, there are 12 countries with some type of national EML.

The following table demonstrates the Arab countries with National Essential Medicines list and the level of income for each country.

Table 4.5: Arabic countries Income Level

Country	WHO Region	Income level (World Bank Ranking)
Sudan	Eastern Mediterranean	Lower middle
Yemen	Eastern Mediterranean	Low
Syria	Eastern Mediterranean	Lower middle
Egypt	Eastern Mediterranean	Lower middle
Jordan	Eastern Mediterranean	Lower-middle
Lebanon	Eastern Mediterranean	Upper-middle
Tunisia	Eastern Mediterranean	Lower-middle
Morocco	Eastern Mediterranean	Lower-middle
Bahrain	Eastern Mediterranean	High
Oman	Eastern Mediterranean	High
Iraq	Eastern Mediterranean	Upper middle
Saudi Arabia	Eastern Mediterranean	High
Kuwait	Eastern Mediterranean	High

Source: Data extracted by author from the World Bank website, 2014.

To help to understand the impact and the process of operating and launching the National EML, a comparative analysis study between 12 Arab countries' Essential Medicine Lists and WHO Model List has been conducted. The reason behind this comparative analysis is to demonstrate how these Arab countries developed and conducted their own list of Essential Medicines, the procedures they used to adopt the WHO Model EML to suit their health situation and the variations between the National EML and the WHO Model EML. The other reason for choosing these Arab countries in which to conduct the comparison, is because, these Arab countries share very similar health needs to Kuwait and some of them share similar income levels and standards of living. By examining each closely, it was proposed that it might give a helpful indication on how the Essential Medicine List of Kuwait could be presented.

Table 4.6: Arab Countries Essential Medicine against WHO Model EML Comparison Table					
country	**Operational EML Year**	**Committee members No**	**First list and Reviews**	**Total M with dosage form**	**Sections No**
Sudan	2007	N/A	1982	543	28
Yemen	2007 (4th)	Not Available	1986	419	27
Syria	2008 (7th)	N/A	1988 (1st List)	1180	33
Oman	2009	10	1995	1103	
Egypt	2006 (2nd)	45	First 1998	579 (2nd) 453 (13/14)	18
Jordan	2011 (4th) (2nd operational)	32 (various committee)	First 1999	635	17
Lebanon	2014	7 (Editorial Committee & Experts Committee)	2002 (no reviews for 12 yrs)	310	14
Tunisia	2008 (2nd)	N/A	N/A	2310	16
Morocco	2008	N/A	N/A	270	
Bahrain	2009(1st)	15	2009	1045	161
Iraq	2010(1st)	N/A	2010	2300(?)	18
Saudi Arabia	2012	Multiple committee (Dr's, Pharm's, Nurses)	2011(1st)	183	29
WHO model List	2015	15 core + 4 temporary	1977	410	30
Source: the information gathered by the author from all the listed countries official source for nEML					

The following represents the timeline of the EML in the Arabic countries, it's apparent that at the beginning, only countries with limited financial resources adopted the list, but as time went by and the EML proved its efficiency and benefit, more and more countries are adopting the concept and in the recent years, wealthy Arab countries are implementing the concept as well. The reason behind this can be explained by the time evidence of the effectiveness of the EML; it's not only useful to make medicines accessible but it also helps in having better control over medicines, support budget management and provides better understanding of medicine quality and adverse effects.

Figure 4.5: EML launch in the Arabic region timeline

Source: The figure was created by the author based on the information from the official listed government nEML documents.

The comparative table above demonstrates several variances in the way the medicines are sectioned, members of the country's own expert committee and the number of medicines on the list. For this reason it's necessary to look closely at each country's experience and the process adopted by the healthcare officials to design the final form of the list.

It's obvious that there are large variances in the number of medicines in the list, if we cross-compare the number of medicines against the income level of the country the result is demonstrated in the following table.

Table 4.7: Arabic Countries cross table of Essential Medicines number against Income level

Country	**Total M with dosage form**	**Income level (World Bank Ranking)**
Yemen	419	Low
Sudan	543	Lower middle
Syria	1180	Lower middle
Egypt	579	Lower middle
Jordan	635	Lower-middle
Tunisia	2310	Lower-middle
Morocco	270	Lower-middle
Iraq	2300(?)	Upper middle
Lebanon	310	Upper-middle
Bahrain	1045	High
Oman	1103	High
Saudi Arabia	183	High
Kuwait	N/A	High

The table was created by the author based on the information from the official listed government nEML documents

It can be stated that there were no significant findings or patterns found between income level and the number of Essential Medicines on the list. They

are all more than the number of medicines on the WHO Model EML with the exception of Lebanon and Saudi Arabia. Syria and Oman where the number was similar and the same was found in Iraq and Tunisia.

From examining each list, one reason was found which can explain the large number of medicines in some lists, that in some of the nEML's, each dosage form has been listed as individual medicines, whereas in other lists the pharmacological identity of the medicine only is considered as an item.

The following is a brief description of each nEML; which briefly includes background information, the timeline of when the list was attempted and the way the list is divided. Up. The information was difficult however to obtain, the reason behind this is the fact that the information is not well-documented and not many publications exist, if any. Another problem that occurred, when collecting the nEML information, is that the Moroccan and Tunisian information was written in French, as a result Google translate had to be used to explain the material, which in translation of pharmaceutical information was not always easy to understand.

The National Essential Medicine List, described below, is arranged from the earliest ones to the most recent.

4.3.1 Sudan Essential Medicine List

Sudan can be described as a lower-middle income country and the largest Arabic country in size, there are a large number of rural areas and the access of medicines to the many villages can be challenging. 5 years after the WHO published the First Model List of Essential Medicines, Sudan launched their own National List of Essential Medicines, the information but the process of implementing the list is not however clear and not well guided, and therefore, the introduction of the list was not operational and no official adaptation took place for some time. However later, in 1987, the list was revised by the Standing Committee for Drug Products Registration, at that time the Sudanese Ministry of Health were more involved and pushed the enforcement, and combined the launch of the new list with Ministerial Order No 7 dated 15th

October 1987. The list was printed in English, and was distributed to all healthcare facilities (Sudan MOH, 2007).

There were more revisions following this in 2001 and 2004, the extent of how many of the medicines procured depended on the Essential Medicines List was not found in the literature.

The medicines in the list were divided in accordance with the level of usage; and the following outline is the way it's been divided:

- *AA: Medicines used in primary health care units, dressing stations and all other health institutions.*
- *A: Medicines used in dispensaries and health centres run by medical assistants (in addition to AA medicines).*
- *B: Medicines used in rural hospitals and health centres run by medical officers (in addition to A, AA medicines).*
- *C: Medicines used in hospitals with specialist departments (in addition to A, AA, B medicines).*
- *S. Medicines used in specialized centres or specialized units in some designated hospitals (in addition to all other essential medicines).*(Sudan MOH, 2006)

4.3.2 Yemen Essential Medicine List

Yemen adopted the first list of medicines in 1986, making it the second Arabic Country to adopt the programme (HV Hogerzeil et al, 1989).

The essential list of medicines includes 419 Essential medicines, and is divided into 27 sections, and the list is presented in table form and has sections for Drug Name, Form, Strength, Unit, level and a code to indicate its priority level. The codes are;

- V, Vital Medicine.
- E, Essential Medicine.
- N, Necessary Medicine.

- The medicines on the list are either in single dosage form or in fixed combination dosage form. There is an extra section to give guidance for prescribers on which drug is more favourable or give warnings to its use.
- A study conducted by Hogerzeil, demonstrated that the adaptation of Yemen to the Essential Medicine List had a positive impact and enhanced the availability of medicines and rational drug use in peripheral health areas in Yemen (Hogerzeil HV et al, 1989). Another literature review conducted by Le Grand, demonstrated that doctor's knowledge of medicines had improved and more rational prescribing has taken place (le Grand A. 1999).

4.3.3 Syria Essential Medicine List

Syria did take pride in being able to produce 88% of the total medicines needed in the country and they were aiming to make it 100%; the medicines that are not manufactured in Syria are classified under four classes of medicines, the classes are as follows:

- Insulin.
- Vaccinations.
- Blood products and plasma substitutes.
- Some anticancer medicines (Syrian EML. 2008).

Syrian Ministry of Health realised the need to have a list of medicines that are essential, some time ago and for this reason they published their first list in 1988, and at the same time introduced a government law to enforce its application. A second revised list came out 4 years later and a third one in 2001, 8 years later. The Syrian Essential Medicine List and its selection were mainly based upon on the WHO model List of Essential Medicines in combination with the knowledge and expertise of the local health professionals (Syrian EML. 2008).

The list is divided into 33 sections in accordance with the pharmacological properties but there is no indication of the dosage form. The medicines are listed in generic names and no trade names are included. This could be due to the fact that most of the medicines on the list are made locally.

It is quite admirable that the Syrian local production of medicines is almost self-sufficient but its raises concerns in terms of the quality of such local productions and the fact of whether they are good enough for human use, stable enough for storage and transportation and hold a reasonable and acceptable safety margin. However, the developments in Syria, before the conflict should be taken into account in developing the Kuwait EML, because of a number of similarities between the countries.

Obviously following the crisis in Syria and the war, all has changed and the innovation has halted, and this is understandable in relation to the fact that war and conflict destroys hospitals, water and sanitation systems and drives health workers away from combat zones, and that has led to totally destroying the country's infrastructure, to include healthcare (Health Alliance International, 2015).

4.3.4 Oman Essential Medicine List:

The Sultanate of Oman is a high-income country with a population of 4 million (The World Bank, 2014). According to the Oman Ministry of Health the Public Health Sector has advanced intensely in the past 25 to 30 years (Oman National Drug Policy, 2000). From these points it indicates that it has many similarities to Kuwait

The Oman MOH Approved Drug list contains 500 Chemical Entities and over 900 Medicine products. The first list was published in 1995, but a revision followed resulting in the reduction of 100 items and a rejection of 150 new medicine applications. A committee named The Central Drug Committee (CDC) is responsible for the selection of medicines. The committee is composed of ten members, headed by the MOH undersecretary, physicians, pharmacists, pharmacologists, the director of Medical Stores and the Director of the Pharmaceutical Sector.

4.3.5 Egypt Essential Medicine List:

Egypt has a much larger population than Kuwait and the income levels vary considerably across the country at the time of the EML. But there are some lessons to be learned by Kuwait. The work of the introduction was much

earlier than many similar countries and the first list was published in 1998, the objective at that time, according to the Ministry of Health and Population (MOHP), was to enhance access and availability of good quality medicines that are related to the health needs of the population. The MOHP believed by doing so and having a smaller list of medicines the cost would be reduced and more funds could be available for other health care requirements (Prof. H. E. Gabaly, 2006). This again could be a consideration that the MOH may find beneficial.

The Egyptian National Essential Drug List was divided into three parts; the first part contained medicines listed under generic names together with; the concentration, the appropriate dosage and the level of the medicine. The second part contained the Medicines Monographs. The last part covers the medicines written under trade name.

Medicine use was organised by assigning each medicine to a level of healthcare, and three levels were identified as follows:

1. For use by all medical professionals.
2. For use only by medical specialists and consultant physicians.
3. For use only by consultant physicians.

4.3.6 Jordan Essential Medicine List:

Pharmaceuticals takes up a large percentage of Jordan expenditure on health, as is the case in Kuwait and it's estimated that in 1998, 2000 and 2001 Pharmaceuticals accounted for 30-35% of the total Jordanian Health expenditure (Jordan Rational Drug List V1, 2006). For this reason and with the technical help provided by the Partners for Health Reform plus (PHR*plus*), Jordan developed its first EML which was published in 1996. Then amendments were made in 2001 and 2002, but neither was made official. The reason, according to the Jordan MOH is that at that time, there was a lack of commitment to rational drug use, collaboration problems, being limited by normal boundaries and not willing to take decisions outside the usual scope of the work which had been undertaken at that time (Jordan Rational Drug List V1, 2006).

Again the selection criteria, was generally based on the WHO recommendations.

However the first functioning list was published in 2006 and was divided into the following lists:

- Unrestricted Medicine List.
- Restricted medicine List.
- Pre-authorized List.

However as a lesson to Kuwait, a large number of committees were involved in the selection of medicines in the list, the reason given was that each committee was specialised on one section of the therapeutic classes. There were also 17 chairpersons for the 17 therapeutic committees to decide on Standard Treatment Guidelines and medicine choices. Again this is an issue for Kuwait if they decide to follow a similar direction. It was also reported that there were technical committees to decide on medicine selection and there was an advisory board to organise and approve the list. The approach carried out by Jordan can be considered to be wise; as it firstly assembled a therapeutic committee to develop Standard Treatment Guidelines, then developed the NEML based on the guidelines. In assembling the structure of the committees it was clear that pharmacists had a minor role on the committees and the selection of medicines was depended on the influence of physicians.

4.3.7 Lebanon Essential Medicine List:

Lebanon is another of the countries in the Arab sphere of countries which has addressed to problem of medicines control. It is a small country with a very diverse community, which is slightly different to the position in Kuwait, and over the years there has been considerable political instability. Despite this however the country has been able to move forward in terms of its healthcare services, to include the development of an Essential Medicines List and one was first published in 2002. Although overall it took 12 years for the List to be appropriately reviewed and introduced and a more suitable list of medicines has been announced.

However the early lists of medicines in Lebanon were exceptionally small in comparison to the list proposed by groups such as the WHO But the reason proposed was that they were mainly based on chronic conditions only and they included 71 Essential Medicines, divided into 14 sections. This list however remained the same for a long time but finally a new edition was published in 2014, and a wide extension to cover many more health issues was introduced. As a result, the latest List of Medicines includes 310 medicines, but it only took a year to decide upon those which should be included when a group of experts became involved in the decision process. The new list is now seen as more organised and more appropriate to the needs of the country and contains two lists of medicines, a core list and a complementary list and it is containing of 30 sections. There is some similarity to the WHO model List of Essential Medicines. But it is suggested that both the WHO suggested medicines and those particularly appropriate to Lebanon are included. The list of medicines is arranged in three columns:

1- INN of the medicine
2- Dosage form and strength of the medicine
3- Official Status of the medicine (List of Essential Medicines Lebanon – 2014)

The medicines have symbols next to them to indicate the source of financing for each medicine, the following are the symbols used in the list:

- NR: Non Registered drug in the Ministry of Public Health
- R: Registered drug in the Ministry of Public Health
- TB: included in the Tuberculosis Program
- U: provided through UNICEF Program
- Y: provided through YMCA Program
- [a]: indicates that there is an age or weight restriction on use of the medicine (List of Essential Medicines Lebanon – 2014).

The selection criteria was based on the WHO 18th model List of Essential Medicines.

4.3.8 Morocco Essential Medicines List

Morocco is another country which can be considered to have some similarities to Kuwait, although the initial comparison is not particularly obvious as it is a mid-low income, Northern African Arabic country with a population of almost 33 million, of whom 19% live below the poverty line (WHO HAI. 2008). Morocco health expenditure is 6% of GDP (2011), (CIA World factbook. 2014).

Morocco has a National Essential Medicine List comprising of 270 medicines and is written in French. The reason why it is mentioned here is because the Essential Medicine list is applied to the public sector where medicines are provided free of charge (WHO HAI. 2008). The nEML was published in 2008 and is a very straight forward list; it includes sections for drug classes then a section to identify medicines in codes, a section for medicine generic name and the dosage form available. These developments are all areas where Kuwait may benefit.

There are however a number of areas where the MOH in Kuwait should take note and one is that the list doesn't have any warning of age restrictions on the medicines proposed, and doesn't have patient information leaflets to indicate any specific requirement or warning.

4.3.9 Tunisian Essential Medicine List

Tunisia like Morocco is another mid-low income Northern African Arabic country with a population of almost 11 million (CIA World factbook. 2014). It is mentioned here because it has adopted slightly different proposals in its EML.

The Tunisian Government has constructed a team named the DPM, which was comprises of members of the Faculty of Pharmacy at Monastir University and a team of experts from the Tunisia Ministry of Health.

It is reported that the selection process was mainly based on the adaptation from the Belgium Drug Directory; where the work of DPM was to adapt the two lists in a manner that suited the health needs of Tunisia. The

MOH also introduced a procedure for enforcing its use which was based on the guidelines which had some similarity to the WHO Collaboration Centre proposals on registration and regulating of drugs. Although only in place for a small number of years it has recently been updated, which tends to show the commitment to the list, its practicality and efficiency in reality.

The aim of the list according to the Tunisian Directorate of Pharmacy was to promote Rational Drug Use; the Directorate believed that this was achievable if the health workers were provided with independent information on medicines registered in Tunisia (Tunisia EML 2008). One major point which comes out of this and others Lists is that the information provided in the discussion and decision was based upon both therapeutic and economical information. But in Tunisia one of the downsides was that there has been tendency from suggested reports for the recent information available to point to some medicine prescribing favouritism. One aspect of this is that the prescribers have been suggested to base their selection on economic factors rather than quality and rationality.

In Tunisia the medicines in the list are divided into chapters based on their properties. Therapeutic and pharmacological, and some medicines have the letter H next to them which indicates that this medicine is for hospital use. In general the medicines themselves are divided into the following categories:

- Vital Medicines
- Essential
- Intermediate
- Comfort

Each chapter includes an introduction to give; direction in the use of the medicines, the medicine's strength, dosage form and manufacturers. The idea behind including the manufacturer is a technique to promote generic medicine use resulting in better control over medicines expenditure. These proposals also have merit and it is suggested that Kuwait should also to note of the reasons for going in this direction.

4.3.10 Bahrain Essential Medicine List:

Another of the gulf-countries is Bahrain which is located on a small archipelago of 33 islands, with the largest island being Bahrain Island (World Atlas. 2015). The population of Bahrain, in 2013, according to the CIA factbook, was almost 1.4 million.

In Bahrain the Essential Medicine list is part of the National Formulary. However; there were no separate lists found or any indication which points to the medicines in the Drug National Formulary as being Essential. The members of the selection committee are the same, as in Tunisia and comprises of two committees; the first one is the Drug Formulary Committee including 7 members and it was supported by an active participant team of 10 Pharmacists.

The number of Medicines on their list appears to be very large and is presently 1045. But the number is inflated as it includes medicines with both trade names and generic names, and the many different dosage forms for the same medicine.

One aspect of note is that there is no separation between the National Medicine formulary and the Essential Medicine list. Again it is something for the MOH in Kuwait to note as this practice can cause confusion and lack of adherence to quality and affordable medicines. It should also be noted that a National Medicine Formulary is a manual containing fundamental information on medicines but also pharmacological information to all the medicines available in the country, while an Essential Medicine List includes information on the minimum number for quality, safe and efficacious medicines that can satisfy the health requirement of a certain population (R. Laing and K. Tisocki. 2004).

4.3.11 Iraq Essential Medicine List:

Iraq has gone through very large changes to its political identity throughout history; these changes were not gradual and didn’t happen peacefully. Iraq has gone through many wars and faced a number of political transformations resulting in very weak governmental sectors at all levels.

It's is still however classified as an upper-middle income, Middle Eastern country. It, borders on the Arabian Gulf, Iran, Kuwait, Syria, Saudi Arabia, Jordan, Turkey and, currently Kurdistan, following the separation of this region from Iraq and it gained independence. As a result of this with such a large number of neighbours surrounding Iraq, the population is very diverse; and is composes of 75%-80% Arab, 15%-20% Kurds, and around 5% of various backgrounds to include Turkoman's and Assyrian's.

This diversity of the population, the conflict and the lack of organisation has had an impact on the healthcare services and expenditure in Iraq (CIA Factbook. 2015). Recent data has indicated that the Health expenditure in 2013 was 5.2 %(according to the CIA factbook). Also although there has been discussion trying to reduce this expenditure, there are limited medicines structural formats in operation in Iraq.

The recent conflict problems in Iraq have however taken their toll, on the Health System. But there has been efforts in the last 8 years to try to manage health expenditure and published its first List of Essential Medicines in 2010. The effective utilisation of such a list has not been explored yet and no literature is available to describe it.

The EML list which has been assembled has taken the following form and is divided into sections, which again may provide some structure for Kuwait to follow.:

(Priority 1)

Medicines that need to be available at all times and circumstances. They are divided into 3 alternatives.

- A: Medicine of first choice
- A/a: alternative medicines
- A/L: Essential but of limited use

(Priority 2)

Medicines in this section are of verified quality and high safety margin with high cost. For this reason they are available on a limited scale and only

prescribed as a second line in case, if the medicines in the Priority list don't work.

- B: First choice Medicines (Best & expensive)
- B/a: First choice alternative Medicines
- B/L; First Choice Medicines of limited use

(Priority 3)

Includes a complimentary list of medicines.

- C: complimentary
- C/a: alternative
- B/L: limited use

4.3.12 Saudi Arabia Essential Medicine List:

The last of the Arab Countries which was considered in the background study is the Kingdom of Saudi Arabia which is indicated to be a high income Middle Eastern country, bordering the Arabian Gulf from one side and the Red Sea on the other. Because of its oil wealth it is one of the richest countries in the world with a population of 28 million, and according to the CIA factbook the Health Expenditure is 3.2% of the GDP (CIA Factbook. 2015). The total annual expenditure on health (THE) in 2009 was 72.3 Billion Saudi Riyal (SAR) (US$ 19.3 Billion), (Saudi FDA. 2012).

The Kingdom of Saudi Arabia has realised it is important to have a well organised Pharmaceutical Sector and appreciate the impact of such an organisation to the overall wellbeing of the population. For this reason the Saudi Ministry of Health has made a number of changes and improvements in the health sector in recent years to help provide better care.

One of the major pharmaceutical changes that has taken place is the implementation of an Essential Medicine List (nEML), which has played a crucial part in improvement of individuals right to good health and ensuring rational drug use.

The list was last updated 4 years ago in 2011; and includes 183 of what is called Essential Medicines chosen in alliance with the National Standard Treatment Guidelines (Saudi MOH. 2009).

The list was constructed and compiled by the Pharmacy and Therapeutics Committee (PTC). It's an advisory committee which gives recommendations in the formulation of health policies, medicine selection and the therapeutic use of medicines in hospital settings (MOH Formulary, drug list 2012). The committee also has an educational unit; and they continue to provide health professionals with on-going training in the most recent advances in medicines and therapeutics. The committee has a continuous role by providing an updated version of the list, which was set at ideally every two years, but the latest one took 4 years to be updated. The update carried out deletion and/or addition of medicines, as appropriate and the final decision is made by the Committee and is based on the literature and evidence provided by international resources, and many public and/or independently funded National Drug & Poison Centres (Saudi FDA. 2012).

At this point it is useful to consider some of the points which relate to having a nEML in place. One of these is the provision of improved rational drug use. However although it is suggested that there should be an improvement at one level, unfortunately, there are no surveillance protocols to prevent or monitor the wide spread of antimicrobial resistance (Saudi FDA. 2012).

In addition a point which was uncovered is the very interesting fact which could be looked at, is that the Pharmacy and Therapeutics Committee (PTC), is found in each public sector hospital and it includes Physicians, Pharmacists, and Nurses as members; the committee is headed by a Physician (Alkelya M. et al 2015). It is suggested that these two facts can affect the decisions made, the reason being that Physicians can look at the concept of quality, cost-effectiveness and Essential Medicines differently from Administratively trained pharmacist and Health Policy Administrators, there is a tendency among doctors to prefer a wider choice of medicines to prescribe from, which they tend to consider is a restriction.

Considering all the facts mentioned earlier, it's apparent that the duties of the PTC are large and intercalated. This situation can cause misperception of the committee roles and can cause collision between different committee's decisions.

When contacting the Saudi FDA to ask for the official list, the response was concerning. The list has never been made public and not yet operational. All the literature states otherwise, especially as it was reviewed once, but never utilised. Such a situation has been seen in many policies in the GCC regions, the project starts and a specific budget gets allocated, then the policy never gets enforced officially due to many factors. Some of the reasons could be due to management changes, the new management finds this specific project not beneficial; another reason is lack of proper monitoring and involved members loose interest; resistant stakeholders to protect their welfare; running out of funds due to miss-management; issues related to Bureaucracy and the lengthy waiting period for getting approvals to each level of planning. These are some of the major reasons that might cause policies and new innovative programmes to halt; there are many others not so apparent and more specific to each situation.

In a situation like this, the overall management of the health system tends to suffer and loses its efficiency, therefore; it's very important to ensure commitment and desire towards programmes that aim to enhance the health services. This is again a lesson for Kuwait.

4.4 World Health Organisation Model List of Essential Medicines

In this section a brief comparison of the content of the WHO Model List of Essential Medicines against the needs of Kuwait is made and there is mention of how the structure and some details of the WHO List may be used for it health needs. In addition there is discussion of the limitations of the WHO List when discussed alongside the needs of Kuwait.

The WHO Model List of Essential Medicines, provides an example which gives guidance to countries, on a country's medicines needs, generally based on its economic situation, and whether there is a possibility that the

pharmaceutical sector is or may be capable of providing efficient and safe medicines.

The WHO has based their selection criterion on mainly; quality, safety, affordability and suitability. It should be noted that to have a list that contains these criterion; it is only conceivable when the country has a well-established health system combined with supportive and transparent health professionals and decision makers. Another important quality needed to be present, is satisfactory access to unbiased and well documented medicine information.

As indicated earlier in the Thesis the first WHO Model EML was published in 1977, and at that time the list included only 208 medicines, as time went by and medicine discovery advanced, the list doubled in size, but didn't divert severely from the initial list. In the latest list, No19 from April 2015 WHO Model List, there were 410 medicines, a single chemical identity and 485 with repetitions. WHO made a list specific for children medicines, currently the children List of Essential Medicines is going through its 5th edition. In 20th Expert Committee on the Selection and Use of Essential Medicines there were 15 expert members together with 4 temporary members. The latest list of Essential Medicines includes several new additions, an example of the new additions are as follows:

- New treatments for hepatitis C
- New treatments for breast cancer and leukaemia
- Treatment for multi-drug resistant tuberculosis (TB), (WHO. 2015)
- In totally, 36 new medicines have been added to the Model EML
- In the children EML, there were 16 new medicines added (20th WHO Expert Committee. 2015).

The WHO Model List is divided into two sections, the first one is the Core List; which represents the minimum medicines suggested to be required for a basic healthcare system. Medicines on this list are suggested to be of high quality, safe, efficacious and cost-effective (WHO. 2015).

The WHO Model EML comes with a secondary list, known as the Complementary List, this list aims to provide medicines for priority diseases; the diseases which are suggested by the WHO to be the ones that require specific health facilities, special training or special diagnostic tools. Other medicines included in the list; are medicines that need to be given in high doses to be effective and medicines that are relatively expensive.

From the discussions on the selected Arab countries' National Lists of Essential Medicines which were discussed in the last section, some countries have chosen to select medicines which are on the WHO Model EML, and others have added a number which are outside the list, which was completed for a number of reasons as proposed. This is expected because the WHO Model is merely a suggestion and not obligatory and each country found their own way to select medicines and adapted their needs in a manner that was suitable to their own health needs and own health capabilities. It can be suggested that If the NEML is a complete adaptation of the WHO Model List, this would result in failure to reach the objective of the EML concept.

In addition the WHO has tended to tailor its List to the less privileged countries when building up the concept, therefore, the list contains a large number of Medicines to treat Tropical Diseases, and diseases of malnutrition. Currently, many countries with mid to high incomes who have used the concept, of the EML have managed to not only enhance medicine access but improve rational drug use and gave control over the inflation of medicine expenditure.

There are therefore a number of variations between medicines on the WHO model EML and the Arab and other countries mentioned above. Variations are found between the sections of the anti-infective, the cytotoxic medicines and the dermatological medicines (Rianne van den Ham. 2009).

In the latest WHO model list of Essential Medicines, there are several medicines that are not in use currently in Kuwait or have been withdrawn or their use has been stopped. Another observation is that the WHO Model EML has several Anthelminthics, this is not really a major health concern in Kuwait; ring worms are relatively minor and curable with one available type of medicine named Mebendazole, trade name Vermox.

In general the WHO model EML tends to focus on tropical diseases. Kuwait is a desert country with the only water source in Kuwait being the sea which needs treated carefully before supplying it to the population, therefore a large selection of Anthelminthics medicines are not required.

4.4.1 WHO Model List of Essential Medicines for Children

In addition to the Medicines List for Adults, there has been a list suggested for Children in place for some time and it is strongly suggested that Kuwait also has a Medicines List specifically based around children up to the age of 12's needs. It is clear worldwide that the importance of child health is a global priority. The WHO Essential List of Medicines for Children was first approved in 2007 (S. Hill *et al* 2012). The lists from the WHO have since been updated and in April 2015, the 5th WHO List was completed. The List focuses on medicines for childhood illnesses and has included those that are rarer and these are listed under what are known as Orphan Diseases and treated with Orphan Medicines.

4.4.2 Selection of Orphan Drugs

EU legislation defines an orphan drug as one that could treat a disease with a prevalence of less than 5 per 10,000 of the population (S. Bojakowski, J. Spoors 2013).

Since Kuwait depends presently on many USA Food and Drug Administration decisions, it is sensible to give the USA FDA definition of an Orphan Drug, which is 'a *drug or biological product ("drug") to treat a rare disease or condition upon request of a sponsor.'* (USA FDA, 20015). The USA FDA goes on to define a rare disease as being; '*A rare disease is generally defined as a disease which affects fewer than 200,000 Americans a year.'* (Gayatri R. Rao. 2015).

The decision on Orphan Drugs is however different between Europe and the USA which view rare diseases and Orphan medicines differently, and it is proposed that when an EML is discussed in Kuwait these differences should be considered and thus it may be the case that Kuwait develops its own definition.

When contacting Kuwait Central Medical Stores, during the course of the Thesis study, who are the sole supplier of Public Sector Medicines, they responded by stating that the CMS have a link with Offices in London and the USA. These Offices deal with special cases and rare disease, the actual duty of these Offices is to order specific medicines for specific patients after going through the appropriate procedures. The medicines are then picked up from the suppliers quickly through a specific delivery company and immediately sent to the Health Centre in Kuwait for that specific patient. However at present this process doesn't have a budget limit, it can be very costly and the regulations are not very specific. It can depend solely on the discretion of the Head of the Office. As has been indicated above it is another area which should be examined more closely and greater control actioned on the handle this process, with better written documentation and control.

This lack of control over prescribing in Kuwait is a wider issue than just for Orphan Medicines and is shown up in many of the requests and delivery processes in place in Kuwait today. In particular practitioners are allowed to order any type of medicine, even if its safety profile has not been fully documented. Such practices are known to apply strains to the medicine budget, especially if a large percentage of the new medicines are very expensive.

4.4.3 WHO Model list of Essential Medicines and Kuwait List of Medicines:

In this section there is a description of the differences found between the WHO Model List of Essential Medicines and Kuwait List of all medicines.

There are medicines widely used in Kuwait which, demonstrated quality, efficiency and safety but they are not available in the WHO model EML. For this reason it is proposed to be significant to look at prescribing statistics in Kuwait's and medicine consumption rates when selecting medicines on Kuwait national EML.

The problem with this statement is that post-market efficiency evidence is not documented in Kuwait and the only way to reach this evidence is through practitioners and Pharmacists' experiences. But this can be biased or not scientifically acceptable. Another option was to conduct a survey among

patients and compare it with the consumption rate of that particular medicine. But the problem could be that some patients might lack objectivity to provide a significant evidence of the medicines choices. The reason could be due to the fact that some patients might be influenced by external factors, such as publicity campaigns to promote specific brand of medicines or the influence of fellow-patients and follows their none-expert opinion on medicines and treatments preferences.

The table in the following page demonstrates some medicines that are on the WHO model EML and are not being used in Kuwait, and demonstrates other medicines being used in Kuwait which are not considered essential medicines by WHO., this type of table comparison might help in distinguishing the variances in the WHO Model EML and the health requirements in Kuwait. As mentioned earlier that the WHO Model EML is primarily presented with limited resources countries in mind, for this reason this list might not be suited as it is to Kuwait health requirements.

Table 4.8: Some examples of the differences between medicines on the WHO EML and the medicines used in Kuwait		
WHO EML	**Kuwait (common M)**	**Only in KW (not on WHO).**
Senna	deleted	
Charcoal, activated powder	Only in private sector.	
potassium ferric hexacyano-ferrate(II) - 2H2O(Prussian blue)	deleted	
olefomepizole	N/A	
sodium calcium edetate	Not Available	
Anthelminthics (12 Medicines)	Vermox (only one)	
clofazimine	N/A	
ethambutol + isoniazid + pyrazinamide + rifampicin	available	Several combination available in WHO EML
Capreomycin, cycloserine, delamanid, ethionamide, kanamycin, levofloxacin, linezolid, p-aminosalicylic acid		Several anti TB combination and single compounds,
Flucytosine (antifungal)	N/A	
Antiretroviral medications (12 medicines and 6 combinations)	3TC, Lopinavir+Ritonavir (Kaletra), Kivexa, Truvada, Efaverinz 200mg/600mg (Stocrin) Etravirine 100mg (Intelence), Combivir (3tc+Azt), Abacavir (Ziagen) Atazanavir 200/150/ 100mg (3 Strengths) Ritonavir 100mg (Norvir), Stavudine 40mg (Zerit), Tenofovir 300mg (Viread) Trizivir, (HIV)Rilpivirine, (HIV) Eviplera, (HIV) Maraviroc 300mg (Selzentry), (HIV) Darunavir)	(HIV)Emtricitabine 200mg (Emtriva), Fosamprenavir 700mg (Lexiva|Telzir), Amprenavir (Agenerase), Nelfinavir 250mg (Viracept), Neviapine 200mg (Viramune), Zidovudine 100mg (Retrovir), Gemifloxacin (Factive) 320mg,
Anti-hepatitis	11 formulation and combination for Hepatitis Vaccine	
Diloxanide (Antiamoebic)	N/A	
Miltefosine, Paromomycin, sodium stibogluconate (antiprotozoal)	N/A	
Amodiaquine, artemether, artesunate, primaquine, (Antimalarial)	N/A	
African trypanosomiasis treatment (8 medicines)	Not available/ not required	
Japanese encephalitis vaccine	N/A	
Source: the data were collected by the author from the WHO EML Library and Kuwait CMS drug catalogue		

As has been stated at the beginning of the Thesis, and based on the information gained from Kuwait MOH Central Medical stores, The State of Kuwait Ministry of Health does not have an exact form of Essential Medicines List. The only record available is the Medicine Catalogue in an electronic form and this is available to the staff of Central Medical stores. The comparative table above demonstrate the differences between the WHO Model List of EM and Kuwait Medicine Catalogue, and it's evident that there are considerable variances between the two. As has been said previously the reason can be explained in a way that the WHO works to target the less resourceful countries and these countries might faces challenges which are different from Kuwait, such as sanitation issues, lack of clean waters, malnutrition and some might suffer from a high level of HIV positive patients and differ in the none-communicable diseases patterns. For instance, in the WHO model List, there are 12 different types of medicines to treat ringworm, whereas in Kuwait one type of medicines been regarded as sufficient.

4.4.4 Kuwait M.O.H. Central Medical Stores Medicine Catalogue:

The following is a List of Medicines which is currently held within Kuwait and the Catalogue consists of 909 pages, and the pages are classified according to store number, and in accordance with the class of medicines or their usage.

There are 38 stores, which covers everything the M.O.H. requires in terms of medicines and medical appliances. The following are the numbers of each store and what it contains:

- Store 01, Narcotic
- Store 02, Injections
- Store 03, Oncology
- Store 04, Specialities
- Store 05, Nutrition
- Store 06, Vaccines
- Store 07, Tablets
- Store 08, Medicines for Diabetes

- Store 09, Surgical Dressing
- Store 10, Intensive Care Anaesthesia
- Store 11, Respiratory System
- Store 12, missing
- Store 13, Liquids & Chemicals
- Store 14, Missing
- Store 15, Forms and Lists
- Store 16, Cardiovascular (largest with the most items)
- Store 17, Sterilization Disposables
- Store 18, Lab. Utensils
- Store 19, Lab. Apparatus
- Store 20, Lab. Analysis
- Store 21, Lab. Liquids. INFL, Acids
- Store 22, Lab. Media-Bacteriology
- Store 23, Lab. Reagent-Cold Items
- Store 24, Miscellaneous
- Store 25, Dental
- Store 26, Surgical Instruments
- Store 27, X-Ray Films, Chemicals
- Store 28, Orthopaedic
- Store 29, Miscellaneous Disposables
- Store 30, Sutures-Syringes-Needles
- Store 31, Equipment’s Various Utensils.
- Store 32, Psychotropic Drugs
- Store 33, Dental Equipment’s
- Store 34, Gases
- Store 35, Artificial Kidney
- Store 36, Reserved Items
- Store 37, Insecticides
- Store 38, Preparation Items

The Kuwait Central Medical Stores deals with all health requirements for Kuwait, and the classification of each store is rather general, and would benefit from further justification of this arrangement.

It was indicated during the interview with the director of Kuwait CMS, that the actual running and logistics of the stores has being subcontracted out to a privately owned company called Agility Co. However there have been questions raised as to the value of this decision as the staff of this company, has limited medical or pharmaceutical experience. It has been suggested that the Store is been run on a format where the store keepers specific responsibilities being assigned to them by the medical staff at the CMS.

Therefore from the information found in the literature study so far there may be some concern for the choice, organisation, management, supply and medical usage of medicines. These areas form the major topics in the research which was carried out.

In the following section, the medicine situation in Kuwait as found through this research is given. As an initial part of the study the views of Health Professionals was pursued and the first research involved two questionnaires. These consisted of, a qualitative semi-structured interview protocol and an informal/conversational interview (no pre-set questions). The following is the outcome of this part of the study.

4.5 Kuwait Health Situation

This stage is related to Kuwait Health; and is an introduction to help in understanding the actual medicine situation in Kuwait. Firstly a brief description is provided through the demographic of Kuwait, and includes a description of the healthcare system in Kuwait, including the pharmaceutical sector. It describes any available policy and future policies, the general budget of Kuwait MOH and the medicine budget changes over the years. In the last section of this chapter, the findings of the study conducted are included.

Kuwait is a small oil-wealthy country located at the Arabian Gulf; as from January 2016, the population of Kuwait was estimated to be 4 million, this is an increase of 4.79% from 2013. Two reasons caused this increase, one is the

reduced number of stillborn infants and the increased number of childbirths. The second, is due to an increase in the net migration for economic reasons. It was announced by Kuwait official resources that in 2015, 114 thousand people moved to Kuwait for work (Countrymeters, 2016).

This increase will possibly cause a strain on resources and services, and that includes Health and Medicines.

The ethnicity in Kuwait is very diverse, Kuwaiti people represents only 31% of the population and the rest of the population are people who came to work in the country. Most of them are Asian at around 38% of the increased number, the next are the Arab workers which represents 28% of the total population. (The statistics for 2013 are provided by the U.S. Dept. of Commerce, 2015).

It’s important at this stage to discuss and explore the Kuwait Healthcare Public Sector. Kuwait is divided into six health districts:

1. Al-Jahra Health District
2. Hawalli Health District
3. Farwaniya Health District
4. Capital Health District
5. Ahmadi Health District
6. Al-Sabah Specialized Health District (Kuwait MOH 2016)

The following map represents the geographical locations of these Health districts.

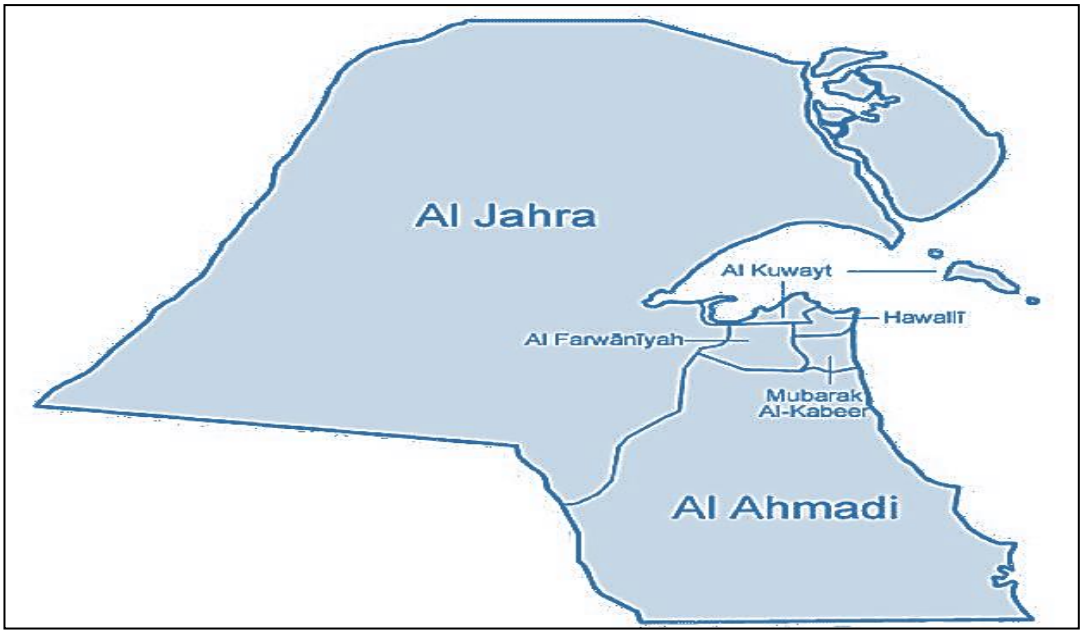


Figure 4.6: Kuwait Map demonstrating the various Health Districts

Some of the health districts in terms of land mass are very large and the reason is that Al-Jahra and Al-Ahmadi are less populated than the other Health Districts. Because of nature of the areas they cover and as they contain many of the oil companies, urbanization of these two districts has been found to be challenging due to the difficult geological structure of the sands and any buildings are generally very unstable.

The Healthcare Sector at Kuwait MOH is divided into three levels of care, the primary healthcare is represented by multiple polyclinics which are spread across the country and serve each region, the secondary healthcare service which is provided by the general hospitals, one in each health region and the tertiary system which consists of specialized healthcare hospitals, which are mainly located in Al-Sabah Region, which is the center for the tertiary health care region.

The treatment and health services are free for all Kuwaitis. But the expatriate's in the country need to pay a yearly small health insurance fee to enjoy all the available health services. They do however have to pay a small fee of one dinar equivalent to two pounds for admission to the polyclinic, and double this fee to gain health support in the hospitals. But this small fee includes doctor visits, nurse care, medication regardless of the cost, and tests.

There is also a fee for expatriates when there is a need to use specialist medical services, such as MRI, but all other services are included in that small fee.

The system above was introduced; to try to reduce the number of unnecessary visits to the polyclinics. Prior to the fee system being introduced, patients would try to bypass the polyclinic and aggressively demand prescriptions for ailments, even those of a minor nature such as a common cold medications or even minor pain killers. Often their prime reason for doing this was to maintain a stock of these medicines for later use at home. But after the fee system was introduced the number of these patients has reduced dramatically. The introduction of the Fee payments also put pressure on the Medical Staff in the healthcare centers, because it led to a new problem of higher expectations of patients, who now suggested that because they are paying the fees they are entitled to get medication on prescription for all health problems, not just for the condition they are currently suffering from, but also medication for all future complaints. Because of these issues the Medicine and the overall MOH budget for healthcare did not reduce, but continued to increase (Kuwait FDA, 2015).

The following figure shows the increase in the MOH budget from 1995 until 2013.

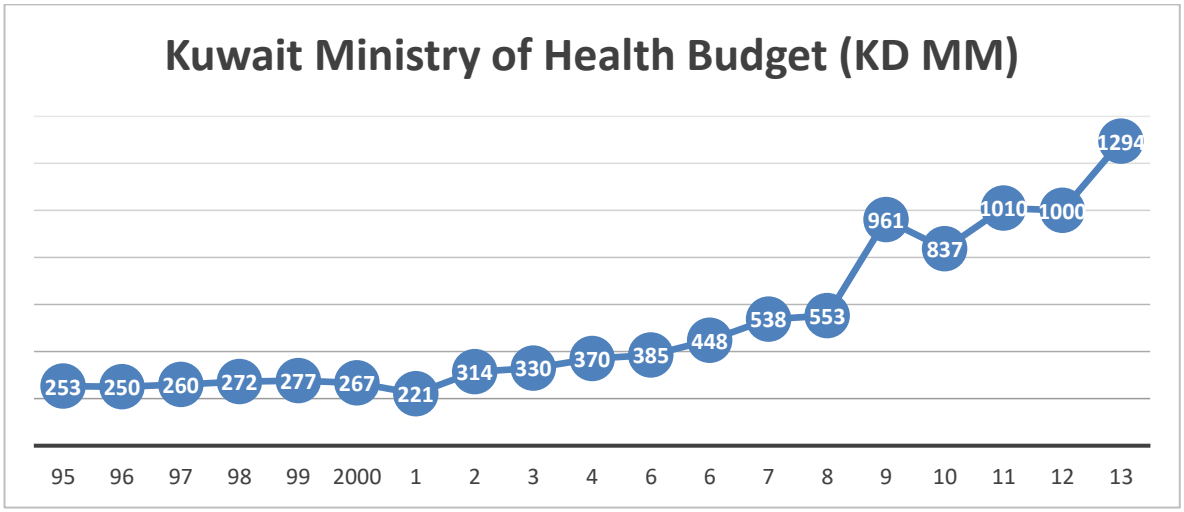


Figure 4.7: Kuwait MOH Budget from 1995 until 2013
Sourced from Kuwait e-Government website: http;//www.e.gov.kw/
And U.S. Department of Commerce/ international Trade Administration

It’s evident that the Budget inflation kept on increasing strongly from the turn of the millennium, and there was a particular, large jump, in 2009 then continuous large inflation after that year. The Compounded Growth Rate (CAGR) is demonstrated in the following table

Table 4.9: Kuwait The Compounded Growth Rate (CAGR) from 1995-2013	
Compounded Growth Rate	**%**
95-00	1.05
00-05	7.59
05-10	16.79
10-13	15.65
05-13	16.36
95-13	9.48
Sourced from Kuwait e-Government website accessible: http;//www.e.gov.kw/ And U.S. Department of Commerce/ international Trade Administration	

From financial forecasts (U.S. Department of commerce} carried out in recent years it is expected by projecting the statistics shown above, that if the Compounded Growth Rate (CAGR) stabilizes at 7% which is about average using todays increases, the budget of Kuwait MOH will be USD 18 billion by the year 2030. That is extremely large for a country with a relatively small population close to 4 million and such a financial cost is likely to cause serious probably uncontrollable strains on the MOH budget and the overall total government budget.

Therefore it is suggested to be important to look closely before major issues arise, by comparing the increase with the actual general budget of the state of Kuwait, and how they may fit together.

The following bar chart was sourced from the Kuwait Ministry of Health website (*www.moh.gov.kw*), it demonstrates how the MOH budget fits with the general budget of Kuwait from 1995 until 2013.

The bar-chart in figure 17 shows that the Government of Kuwait has kept the percentage of the budget allocated to the health services almost constant

and the government of Kuwait is the sole funder of Kuwait MOH budget, the maximum it reached was 7.4% in 2010, and the least was in 2009 with 5.3% and 2007 with 5.2%. Therefore, the increase of the MOH budget was due to an increase in the total government budget, which is related to the oil situation and Oil revenue, what is meant by this is that when the Oil income increases the total government budget increase and vice versa.

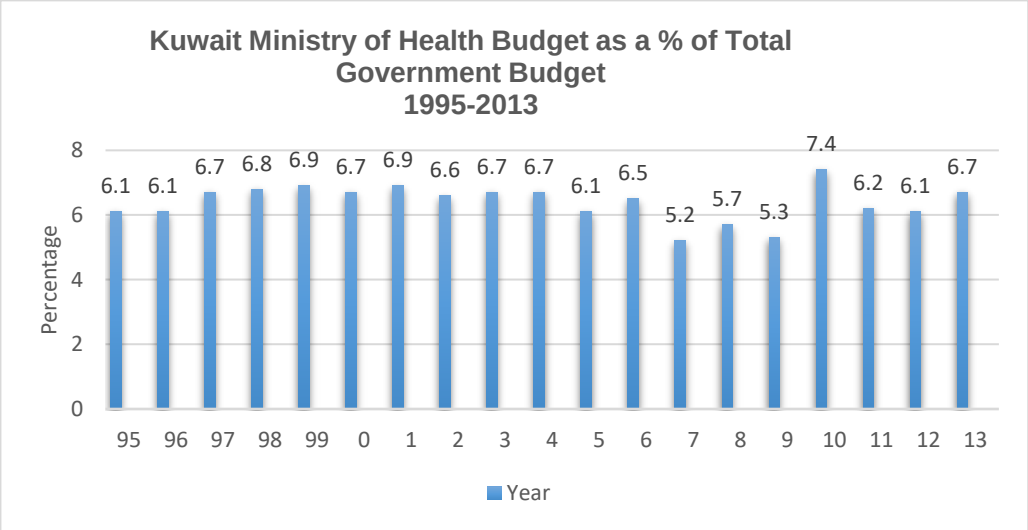


Figure 4.8: sourced by author from the official Kuwait Ministry of Finance

At this point, from the information above it is safe to say that the budgets of the MOH and for Medicines from the main Government budget are almost stable, but the main budget is the one that is inflating drastically, and it is this that needs control and deliberation. In other words it's a national effort and serious studies and policies need to be operated to control future situations.

How has the problem been dealt with, the simplest method when oil revenues are high has been for the Government of Kuwait to attempt to enhance the health services has allocated a large amount of money which has particularly improved the healthcare centers. It has allocated 4.4 billion U.S dollars for the expansion of several secondary healthcare hospitals to keep up with the demands, and to provide more beds.

This move is a great attempt to provide improved health to the population, but there are other options such as giving the primary polyclinic

more authority to treat late stages of chronic diseases, rather than referring to them to the secondary healthcare hospitals and increase the pressure of demands. Looking closely at this move it is however suggested it would be better to encourage a number of initiatives, such as more preventive care rather than curative care, spending some funds to enhance the public awareness to health matters and educating them on healthy life choices should reduce the demands on the health services and provide a healthier population with suitable knowledge of healthy life choices.

Another way which could be used to try to enhance the health services is by trying to find and reduce the area(s) that drains most of the funds, and to try to come up with the most appropriate policy to overcome and control the situation. There are a number of areas where the MOH resources are being drained. One major reduction could be a program to deal with the costs of treating Kuwaiti patients outside of Kuwait. This program has been very expensive and has caused a major strain on the budget. Once the patient is back in the country, the costs have not however finished and the Pharmaceutical sector is responsible to provide that patient with possibly all kind of new medications some of which are very costly and may not have been fully studied post-market. This has been a very big additional cost on the Medicines budget.

Another source of MOH budget drainage could be from, what is known as the Visiting Visa Patients, those are non-residents and non- Kuwaiti patients, who travel to Kuwait to enjoy the almost free health services and gain access to very expensive medicines at the cost of one Kuwaiti Dinar which is an equivalent of two pounds only. As a costly example some prescriptions for organ transplant patients might cost in the region of 500 Kuwaiti Dinar which a little more over a thousand pound, and the visiting patients can get access to these medicines for as little as only 2 pounds. It can be the case that these visiting non-Kuwaiti patients come to the country every three months for prescription refills. In some healthcare centers, these outside patients can receive a 6 months' supply of medicines. This leads to a very high cost for the MOH and it's like the Kuwait medicine budget is not only allocated to the population of Kuwait, but it has also to cover the high cost of non-Kuwaitis who

only appear to come to the country to receive unlimited costly medicines. In addition other international patients can get access to the service (Kuwait MOH, 2015). These situations are of concern to the people in the MOH and to the people of Kuwait and it is suggested through this research work that it is something which needs further study and possible curtailment.

In discussions during the Thesis study it was indicated that the Kuwait MOH realizes that this situation needs to be resolved and have tried to find a solution. One step taken was to increase the polyclinic admission fees for non-residents to five Kuwaiti Dinar which is close to 10 pounds and for hospital visits it's been increased to ten Kuwaiti Dinar which is equivalent to 20 pounds But against the actual cost the return is low and for outsiders it is an increase which is still worth paying to get the extremely expensive medication. Therefore, the problem is still there and was not discouraged by the administration of the 5 KWD and 10 KWD admission fees.

Reflecting on the discussion above, it's apparent that the budget inflation is to many aspects and from the information obtained through the research study there is a question around the lack of efficient planning and there should be considerations relating to management. It has been found that there are limited clear policies in place, and policies that in place often go into a holding format with every change of the Health Minister, which can occur regularly. A typical example was the launch of the Pharmacovigilance Department and the Medicine Index Department in 2013 and subsequent stalling of the work of these Departments in two policies that will be discussed later in the Chapter.

Following the fieldwork in Kuwait, it demonstrated that Kuwait's Pharmaceutical Sector follows a very complex approach. This could be due to several factors but the several interviews carried out with senior managers at Kuwait MOH and Kuwait FDA it gave some evidence to an impression that, the Pharmaceutical sector lacks proper policies and follows very dated regulations that have not changed much over the years and has had many additions made to it, some might seem very contradictory to the original (Kuwait FDA, 2014).

Through on-site observation of the work carried out in Kuwait, it became noticeable that the staffs are following some regulations that are released

separately and not gathered in one written document. This has resulted in missing out on some of the procedures and causes the inability to make a full confidant decision, in case another declaration came out to cancel the current one they are already following, this information was gained following the field work conducted and after the interviews conducted with the Kuwait FDA staff that been assigned new roles to carry out new innovative policies but then been stopped pending further instructions.

4.5.1 Medicine Registration Department:

Located at the Kuwait FDA building, it includes 12 pharmacists and a head of Medicine Registration Department. The duties of this department are to register new medicines by conducting a study on any new medicines that requires marketing in Kuwait, or a pre-registered medicine that had some changes. Another part of these department duties is to update the registration of already existing medicines. The department is also responsible for following any medicine errors that might come up post-market and the withdrawal of unsafe medicines.

The number of staff is rather small in comparison to the amount of work needed to be carried out; the result is a very slow productivity which causes frustration to the recipients.

4.5.2 Deletion of Medicines or Withdrawal of Defected Batch or Manufacturing Error

Kuwait Food and Drug Administration (Kuwait FDA), is responsible for the detection of any medicine errors post-market, there are several reasons why a medicine or a batch of medicines may need to be withdrawn. The following are some of the reasons as described by the staff at the drug registration department at Kuwait FDA:

- Applying changes without obtaining the right licence, such changes are as follows;
    - Changes in one or more active ingredient(s).
    - Addition of new active ingredients.
    - Removal of any existing active ingredients.

    - Changes in quantity of any active ingredients
- The manufacturing company may have detected some fault, vulnerability or defect and sent a request of withdrawal for the medicine or a specific batch of medicine from the market.
- They may have received a warning from the WHO for specific medicines for being troublesome, or problematic.
- They may have received a warning from the USA FDA or EMEA to withdraw a specific medicine after post-market use.

Once the warning is received or the announcement is made by the USA FDA or EMEA, the medicine should be suspended and a recall sent out. This is followed by a meeting at Kuwait FDA to determine the extent of the problem and what is the right course of action that needs to be carried out. Once this is done, the action can lead to either temporary withdrawal until the problem is resolved or a permanent withdrawal and total cancelation of the product license.

There is a division within the Kuwait Medicines Registration Department that deals with such situations, entitled the Quality Assurance Department, and they carry out daily searches of the FDA and EMEA sites to explore any new problems or warnings.

However the Kuwait FDA generally depends solely on the announcements made internationally and has no type of an internal national system to follow the medicine situation locally. The issues around this practice is that Health Regulators in different countries and different ethnicities react differently to medication, what might be considered as safe to one community it might be hazardous to another and vice versa. Although the Kuwait FDA has realise the importance of having a suitable monitoring system and has tried to come up with some solutions and the following describes the attempts that have been made by Kuwait FDA to organise the medicine situation in Kuwait.

4.5.3 New Policies

From the information gained during the study and experience as a managing pharmacist, new and younger pharmacists, many of which have been educated outside the country, are suggesting a number of developments to enhance the standards of the Pharmaceutical sector. These include suggestions to modify the current structure and make it comparable with the surrounding countries who have more developed structures and with the more developed countries. It's now quite typical in Kuwait within the Health Groups, to see a very high level of excitement and encouragement once a suggestion of new policy comes up. But unfortunately the level of excitement can drop down quickly with time. The result is often that the new Policy stays pending with no direct order to proceed (Kuwait MOH, 2013). The following are examples of two important policies that are long overdue and have come to a halt.

4.5.4 Pharmacovigilance Department

4.5.4.1 Interview with the Head of Pharmacovigilance Department in Kuwait FDA

Following the fieldwork visit to the Kuwait Food and Drugs Authority, and the Medicines Registration Departments, one of the areas of concentration was to discuss Policy Development through a closer inspection, with regards to two policies that are supposed to be of added value to the pharmaceutical sector in Kuwait. The interview with the Head was carried out with the pharmacist in charge of the Medicine Index Policy and then later the discussion moved onto the Pharmacovigilance Policy.

The interview was initially non-formal, and more of a conversational interview without prepared questions, but had a specific purpose in mind. The purpose was to find out the several types of policies available at Kuwait MOH, the process of launching new policies, and policy adaptation and implementation.

The outcome of the interview which gives an example of the lack of full development of ideas for improvement in Policy and Operations was as follows:

The Pharmacist stated,

"*The Department is five years old but the number of staff is only two and they are in reality not following the international guidelines*"

And further added that,

"*They are waiting for new operation regulations that follows the international guidelines.*"

The Department which is actually named the Quality Assurance Department was then changed into the Pharmacovigilance Department, the person who was to develop the Department was given the approval from his Senior Colleague to start the Department but no actual plan has been agreed which relates to the structure of the Development and on the duties to be carried out and there has been no discussion of the expected contribution to general health.

The MOH did not focus on the development of the Quality Assurance Department and the later changed into the Pharmacovigilance department, The Ministry of Health in general and the none-pharmaceutical senior managers at the ministry of health, thinks that medicine quality assurance can be tracked by other departments.

It could be suggested that the Pharmacist should have been more pre-active in developing a Plan. However from the interview they gave the reason for not having an operation plan by stating,

"*It's assumed that we are waiting for the Arabic Standard Guidelines on Pharmacovigilance to follow from the proposal, but nothing has been announced yet*."

However, although the duties of the two-staffed Department are not yet fully assigned, from the interview it was clear that they have started to plan and are effectively using their own initiative, although the direction followed may be unstructured and have assigned some non- official duties to themselves. These includes a check daily on-line for any announcements of adverse drug reactions from International Pharmaceutical Companies, and in addition have the self-

assigned responsibility of checking the USA FDA announcements for medicine label changes or warnings on issues such as side effects. This job is already scheduled to be done by specifically assigned staff members at the Medicine Registration Department. Thus there is an indication of inefficiency through the clashing of duties between two Departments and the interpretation is related to the fact that the Pharmacovigilance Department staff has no written job description.

However although the aspect carried out above does need resolution there is one job being done, which is actually related to the duties of this as yet non-structured sub-section of the Quality Assurance Department, and that is the production of a newsletter that carries any instruction or special requirements for any medicine. Example of these requirements can be a form of instructions to the prescribers to perform pre-testing or post-testing of patient's vitals after taking certain medicines that has a narrow therapeutic window or medicines with narrow safety profile, or instruction for medicines that changed in quality or have new safety profile.

Although this newsletter is sent to all healthcare facilities and centers at all levels, the Department still remains anonymous to most pharmacists at Kuwait MOH, this was observed when contacting various pharmaceutical department at the three level of healthcare in Kuwait and the response of the staff where lack of awareness to the newsletter. This might propose that this Newsletter work is unclear or inaccessible to the relevant audience.

The department staff further adds that,

"*Kuwait has no local postmark vigilance, in Kuwait, it all depends on international warnings and instructions"*

This is a problem because each country has its unique genetic disposition and react differently to medicines, therefore; what is harmless to one specific genetic profile isn't necessary safe to another.

One important statement declared by the pharmacovigilance pharmacist is that,

"*This department is not efficiently performing because of lack of ministerial act, if one strong ministerial act comes out, it will be required by law to have specific duties for this department and it will perform better*"

The interviewed staff mentioned that they are ready to take the job especially that they are trained and attended a number of workshops and presentations from private companies.

This is one example of an innovative policy paused for several reasons that will be discussed later; the next policy is having a drug index with the main objective of having a more organized process of classifying medicines in Kuwait.

4.5.4.2 Kuwait Drug Index

The Drug Index plan started around the first quarter of 2015, two pharmacists have been selected to carryout feeding the hard-copies of drug monograms into a computer programme. The work has slowed down a bit and one of the allocated pharmacists has been moved to a new division, this might be an indication that the enthusiasm towards the programme and the support has been lost, the deficiency of interest in the Drug Index plan was observed following the in-charged staff comments stating that,

"The Drug Index plan, was not discussed anymore in meetings, and no further instructions were given to keep going"

There is another issue that caused this policy to slow down. This issue is that the pharmacists involved have not been given any form of written guidelines or procedures to follow, and no training on the concept of a Drug Index design or medicine formulary guidelines. All they got instructed to do was to feed a computer package with monograms of medicines without any thought to the process. With such unplanned protocol, it might be expected for the policy to pause awaiting instructions, the two staffs' in-charge of the Drug Index did ask for training and further instructions but still waiting for a reply from the head of the department.

It seems, from these two attempts to enhance the medicine situation at the State of Kuwait MOH, that the process of implementing had not in these cases has not been efficiently planned and not for various reasons been supported by the strong decision makers to ensure its continuous execution.

Although these examples are only two, from experience and from the other interviews and during other fieldwork, it could initially be suggested that there may need to be more direct attention to the development of proposals which on the face of it appear to be important initiatives within the MOH. For this reason, it is proposed that it may be significant to include the support of high-level decision makers at Kuwait MOH and to be more organised and have a general plan for policy implementation across many facets of the MOH administrative service. With such a structure in place, it could be believed that if the new policy is proposed and gets support, then there should be a structure to support the development with a strong steering group which should improve and might enhance its success rate Furthermore, leading from the study carried out here it might be worthwhile to look more closely at the training and experience required to carry out such developments and to use experienced people, possibly from outside of Kuwait to conduct an initial detailed study, to add positive value to the new policy undergoing implementation.

The following is a description of 6 interviews that been conducted with 6 Health Executives at various levels of management. The section describes the interviewees' views on the EML concept in general and what they might think is a suitable process of implementing EML at the state of Kuwait. The choices of the participants at the interviews were based in the strong leading role of the participants in managing the Ministry of Health pharmaceutical sector and the broad knowledge in health managements and development, it is expected that the participants might be the individuals that can provide a useful and meaningful data to any health related innovation.

4.5.5 Thematic Analysis of 6 Senior Health Executives Interviews.

This section includes the description of 6 interviews carried out with senior managers at the Ministry of Health in Kuwait and one from Kuwait University, Faculty of Pharmacy. The participants were selected based on their

important part in the procurement of medicines and their decision-making strength in the medicine selection process.

The transcripts and field notes were imported into the qualitative analysis software package N-Vivo for coding and data management. The prime aim of using this software is to organize complex research data into different segments to carry out a complex search to meet the aims and objectives of the research. However, this is not an interpretative device and thus the interpretation of the data is carried out after organizing the data with the aid of this device. It is used to work effectively with extensive data and a suitable coding scheme.

4.5.5.1 Generation of Themes and Coding

The themes were generated by using the template analysis procedures and the broad themes identified for the research were named as codes. Each broad theme was analysed with the help of data provided by the participants of the interviews. The codes used for the study were meaningful, regarding the research objectives and questions. The codes that were created for this study are concepts, feasibility, gains, and drawbacks. The participants had a broad range of views on the concept of Essential Medicines.

4.5.6 Understanding the Concept of Essential Medicine List.

The responses in regards to the concept of EML in general were somehow similar, all the participants answered that they have gained sufficient knowledge about the concept of the essential medicine and the benefits of implementing this concept in the medicinal field. In addition, they also have the information about the benefits achieved through implementation of this program. However, two participants noted that the principle is semi-available in Kuwait, those were the undersecretary of medicines and medical appliances and the undersecretary of development and quality at Kuwait Ministry of Health. This is understandable for individuals of that level of management not to declare sides or views before getting a grasp of the complete topic.

4.5.6.1 The View of the Concept of EML in Relation to Kuwait Health Situation.

The general view was that the concept is excellent but it needs to be implemented carefully; there were some differences in the responses, Dr. Omar, who is The Assistant undersecretary of Pharmaceutical and medical appliances expressed his thoughts in the concept as follows;

"It's a list of Medicines with fewer items and more focus on generic medicines. It's very similar to what we practice in out pharmaceutical services, but we established the system our self's"

In Dr. Omar statements, he focused on the fact that EML encourages Generic medicines but he further added that the Pharmaceutical sector has a similar system, it does demonstrate a basic understanding of the concept but the EML does not only focus on Generics it goes further to includes some relatively high cost-effective medicines that Dr. Omar didn't get grasp of it fully, it is understandable since the concept of EML is not available in Kuwait and this was the first time Dr. Omar get an idea about it, therefore in Dr. Omar statement that the system is similar to what is already present in Kuwait is not very accurate.

The second interviewee was DR Al-Falah, who is the Assistant Undersecretary of the Ministry of Health for the Planning and quality Affairs thought that the concept of EML is;

"I think that the concept is suitable to my Department which is Planning and quality Affairs"

The response represents a link between Dr. Al-Falah department with the innovation process and since Dr. Al-Falah is not related directly with the medicines procurement, he was unable to give a clear indication of the EML concept in details but managed to find the link of the EML to its Department duties in relation to enhancing the quality of health services and he believed that the EML will fit well with his department work.

The third interviewee was chosen based on his work in academia and might be the first introduction of the system to young pharmacists if the system get implemented, Dr. Waheedi is the Associate dean of the Faculty of Pharmacy, Kuwait University, his thought on the concept were very methodological and his statement was as follows;

"It's a national drug list, updated every two years"

His response was very brief, precise and practical at this early stage of the interview. He did not comment further on the EML concept benefits but he further explained it at a later stage of the interview that will be quoted later in this chapter under different theme.

The fourth participant was Dr. Al-Qattan, who works as the Head of Specialties Drug section at Kuwait CMS. His response was very brief only one word, this could be because he was extremely busy and there were several interruptions to the interview that was impossible to control, his response was;

"Excellent"

The response doesn't ensure his clear understanding of the concept, but it might indicate that he think it's a suitable mean to innovate or maybe be he doesn't fully acknowledge it and gave a brief comment, when the interviewee were asked to elaborate, he did not add any further comment.

The fifth interviewee was selected based on his position in a tertiary healthcare and direct interaction with medicine supply and procurement, he was the Head Pharmacists of Psychiatric Hospital, and he thought in his own word as follows;

"Good, saves money if fully applied, transparency is a must"

The response establishes a broad understanding to the concept and being able to express the fact that implementing EML requires transparency is a good indication to the desire to innovate and minimize medicines corruption.

The last participant Pharmacist Asma Al-Mutairi was preferred because of her work with the primary healthcare level and she is directly involved with the procurement and usage of medicines and because the primary healthcare is the first level that deals with healthcare recipients. Her thought on the concept were as follows;

"Good, enhance pharmacist role in healthcare"

The response is interesting and referred to a further positive role to the pharmacist in healthcare, this could indicate the well to be more active and the desire to enhance healthcare.

4.5.6.2 The Views on the Possibilities of the Implementation of EML

The code of this section was Feasibility and it was noted that hesitancy was present, and most of the interviewees had concerns, the general theme was that it is possible but requires support at a higher level and needs a ministerial act.

Dr. Omar thought that;

"*The regulations in the ministry of health are very rigid and will hinder the application of this system, we need new law to start the policy and getting new law in place is very difficult.*

Such policy need to get the approval of the government National Assembly (the Parliament) that's a very long process then needs to be passed to the Ministers Council once both approved the law will be stated then it's in the hand of the Minister of Health to regulate it and draw the plan to its various sections.

A special ministerial decree need to be declared from the legal department at the Ministry of Health then it has to go through a committee to implement it.

In short, it's very long, very exhausting and time consuming process"

The response is important, it gives directions to what might be expected, to carry any new policy work, and it states that a lot of time and efforts are expected.

Another high-ranking interviewee Dr. Al-falah thought;

"It requires time and careful deliberation of the whole concept and need very careful planning. It will make a lot of doctors feeling restricted."

This comment was shared with CMS staff Dr. Fahad, who deals with physician requests daily; his statement was as follows;

"Doctors work in a different way; they will question the withdrawal of some drugs and will protest against the limitation to the drugs they are allowed to prescribe"

This is another important matter that requires to be included in the plan, if the EML of Kuwait get adopted, it requires to include physicians during the course of the implementation. This type of involvement might help in easing the way to introduce the concept; it might be useful to gain the support of the physicians early to enhance the success rate of the concept.

Another important thought, stated from an academic point of view by Dr. Waheedi when he was asked whether he thinks that the EML concept can be operational at the MOH, his response was;

"Probably yes, with concerns being that the MOH committees when under taking an assignment they tend to take it as an administrative task rather than scientifically based"

Dr. Waheedi stated an important thought that requires to be considered if the EML concept get implemented, and medicine selection process and medicines policies in general requires the support of a sound scientific

background and good pharmaceutical experience for it to be efficient, basing the work on administrative staff might not be a good way to go.

4.5.6.3 EML Gains

The response was almost unanimous; all the respondents thought it will control cost, enhance medicine access and provide rational drug use.
The CMS staff had further thoughts;

"Save on cost, saves on storage spaces, saves on paper work, decrease drug error, decrease doctors' confusion towards the massive medicine list and makes them more aware of the medicines available. Focus on good quality medicines and eliminate low quality. Prevent stacking of a lot of different generics"

Dr Essam of the tertiary Health centre, thought that;

"Control Medicines prices, control counterfeit medicines, patient satisfaction with the availability of treatment, pharmacist familiarity and knowledge with medicines will increase. Doctor / pharmacist work relationship will be easier and better, because everyone knows its place and role. This will lead to better work ethics and increase the standards of work"

The statement by Dr Essam includes an important advantage to be considered, which is medicine knowledge enhancement and improved trust between doctors, pharmacists and patients, this kind of trust between the healthcare providers and healthcare recipients is always an improvement, and the harmony in the interaction might results positively on the general health.

Reviewing the responses, each respondent saw the impact to their actual work and related the concept to it, this is a constructive way of looking at the concept, it might demonstrate an initial acceptance to the concept and willingness to move forward in the healthcare services.

4.5.6.4 Drawbacks of the EML

The responses in regards to the drawbacks and interruptions that might cause an complication while implementing the EML concept in Kuwait was diverse, but each interviewee regarded the obstacles from own experience and how it relates to the interviewee work field, the main difficulty felt by most respondents is the resistance from the local big pharmaceutical companies; the following quotation from Dr Essam presents this finding;

"Wholesalers will have concerns"

Dr. Al-Falah had a similar but broader view on the matter, his statement were;

"Very difficult to change the current culture and the current system has been the same since the beginning of the Pharmaceutical services, I expect there will be a lot of resistance but it's achievable"

Both participants shared concerns in regards to the resistance to the concept, it is understandable concern and might be useful to figure out what might cause an impediment to the concept at an early stage, it is believed that by doing so, it will help to be ready for any upcoming opposition during the introduction, adaptation and implementation of the concept.

Another view was common along some of the participants, the fact that the process might take a long time;
Dr. Omar stated,

"The law enforcement is very long process, and the minister of Health frequently changes that might bring the whole policy to a halt, when a new Minister of Health get appointed"

And Pharmacist Asma also held similar thought to Dr. Omar; the following is her statement;

"Difficult to implement, takes long time and efforts"

The view shared by Dr Omar and Pharmacist Asma are significant, and it's predicted that a concept with a large scale would requires time to be implemented effectively.

In the other hand, Dr. Waheedi had a different view on the matter, he focused on the healthcare providers and healthcare recipients and his statement was as follows;

"Mainly felt by physicians, and patients. Patients usually have high expectation for treatments received and the whole healthcare experience"

Dr. Waheedi intended in his statement that the downside to the EML concept in his own view and based on his limited knowledge of the concept, might be felt by the healthcare recipients and healthcare providers more and the reason could be explained by the fact that both would like a full and extensive list of medicines to choose from, in reality this practice can be viewed as inappropriate, and multiple-prescribing of different medicines under similar therapeutic class could be unsafe.

Dr. Fahad from the CMS, had different view on the matter and he thought that there might be a major disadvantage to the concept if it gets implemented, the reason in his opinion that the concept encourages generic medicines and since the generic manufacturing companies are able to deliver the supply faster, he worries that the end results might be all generic medicines and no branded medicines at the CMS. His statement was as follow;

"Larger branded company takes long time to supply, generic manufacturers are faster and cheaper, therefore, CMS buy generic. Generics are more variable and reliable. The CMS Will end up with generics medicines only. Senior MOH managers will resist the implementation"

It is true that the EML concept encourages the procurement of quality generics, but it doesn't limit the medicine selection to it. What Dr. Fahad has stated is an important point that requires consideration, if the EML concept get adopted and implemented at Kuwait MOH, it might be wise to include some criteria on the medicine selection procedure to distinguish when it's preferable to select generics and when it's more appropriate to select branded medicines. Another impression coming out of this statement is that there might be important to have written and clear procedures to follow during the process of implementing the EML concept. This practice of having clear and well-written documents might help in clearing confusion on medicine selection and it can be considered as being a well-planned reference to refer to when making decisions relating to the EML.

Overall, the disadvantages or what might make it difficult to operate the EML concept efficiently came down to the long managerial process of getting the concept approved, then the fear of not being able to follow it up competently, the resistance from the healthcare providers and recipients, from the high level management at the MOH and from the major pharmaceutical suppliers at Kuwait.

It's important and valid points and it might be useful to carefully deliberate on them and take these thoughts in consideration, if Kuwait MOH decided to adopt the concept of EML.

The last two points that were part of the interviews were related to whether the interviewee like the EML concept to be present in Kuwait and if that was the case would they like to take part in the process.
The responses were as follows

4.5.6.5 Implementing EML in Kuwait and Being Part of the Process

All participants agreed on implementing the EML and would like to take part in the process. The Assistant Undersecretary of the Ministry of Health for the Planning and Quality Affairs stated

'*I would like to see it implemented but it requires a specific modification to suit Kuwait health*'

This a very reasonable thought and it demonstrated deeper understanding of the concept. On the other hand, the Assistant Undersecretary of Pharmaceutical and Medical Appliances stated that;

'*A big policy such as the Essential Medicine List will require the appropriate committee to get it operational and that must be chaired by the relevant Undersecretary, and in this case will be the Undersecretary of Pharmaceuticals. After all, if anything goes wrong or any inappropriate decisions are made I will be responsible for it.'*

This is a very important addition and gives an idea of the local protocol that needs to be followed in order for the EML to be launched.

The outcome of the interviews were positive, with concerns of resistance from various stakeholders, such as drug companies, physicians with particular interest to specific treatments, patients thinking they are receiving a poor quality of medicine when they get prescribed generic medicines and other people who loses financially from such a concept. The overall thought is that, all support the concept but apprehensive that it might get diffused and halted like previous policies that didn't get implemented correctly and didn't follow the most appropriate method of execution.

The following part is relating to the medicine situation in Kuwait, it will include the outcome of the two questioners carried out in Kuwait; the first questionnaire was conducted to extract knowledge of the overall medicine satisfaction level at the public sector in Kuwait.

4.5.7 Kuwait Medicine Situation Evaluation

83 participants were involved in the evaluation of the medicine supply system questionnaire; the following table represents the different professions that took part in the questionnaire.

Table 4.10: Job title of the participants

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Physicians	27	32.5	32.5	32.5
	Academic Staff	7	8.4	8.4	41.0
	CMS Staff	8	9.6	9.6	50.6
	Public Pharmacist	41	49.4	49.4	100.0
	Total	83	100.0	100.0	

The population of the study chosen based on their direct involvement with the medicine supply cycle. The questions within the questionnaire were aimed to view the degree of satisfaction towards the current medicine supply system and try to identify what issues the health professionals might have with the system. For this reason, different levels of work experience were chosen to ensure diversity in opinions and the following table represents the range.

Table 4.11: Work experience

		Frequency	**Percent**	**Valid Percent**	**Cumulative Percent**
Valid	1-5 Years	21	25.3	25.3	25.3
	6-10 Years	31	37.3	37.3	62.7
	over 11 years	31	37.3	37.3	100.0
	Total	83	100.0	100.0	

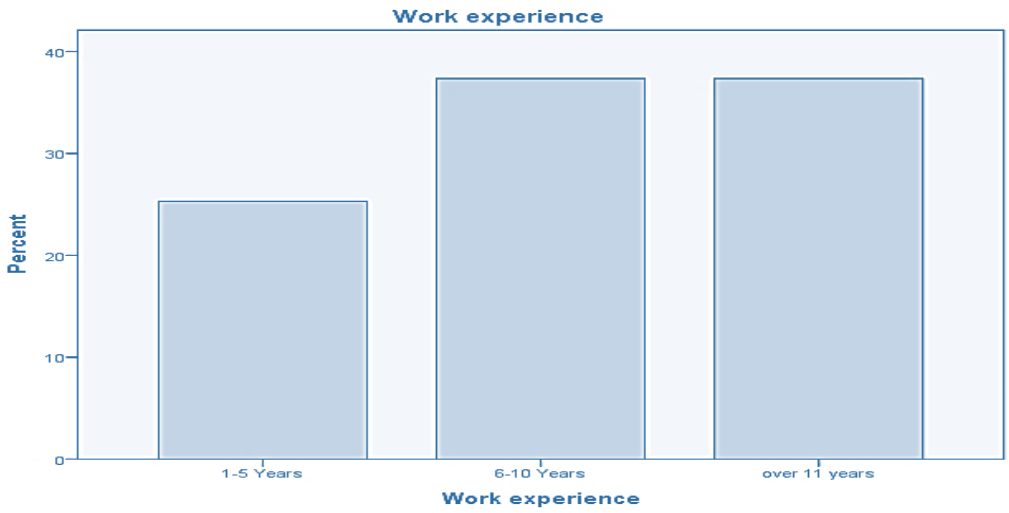


Figure 4.9: the percentage of participants work experience

The majority of the respondents had work experience of over 5 years, this is important to ensure a valid view and good knowledge of the current medicine situation, but it is still important to include the younger healthcare providers to view their ideas and get younger and fresher thoughts.

Looking at the level of satisfaction with the medicine supply system at Kuwait MOH, almost half of the participants were unsatisfied with the current system, and 56% thought that there is room for improvement to the regulations and the system.

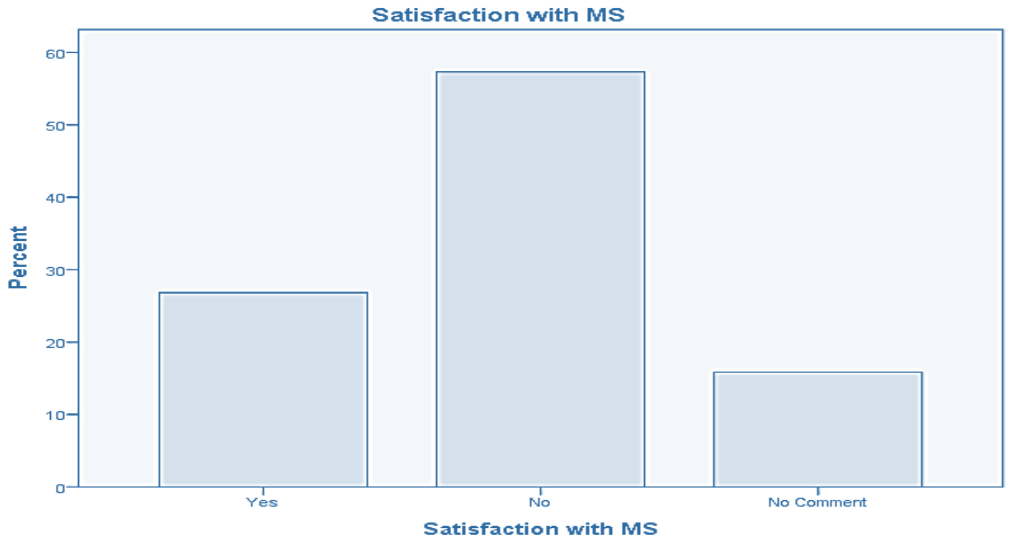


Figure 4.10: Bar chart to demonstrate the participant's satisfaction with the Medicine supply cycle at Kuwait MOH.

Table 4.12: Satisfaction with MS					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	22	26.5	26.8	26.8
	No	47	56.6	57.3	84.1
	No Comment	13	15.7	15.9	100.0
	Total	82	98.8	100.0	
Missing	999	1	1.2		
Total		83	100.0		

The previous bar-chart and table 22 shows low level and almost lack of satisfaction of the current medicine supply situation, this condition is alarming and requires a serious stand and deliberation, there is a need to understand the reason behind such a response and since half of the staff at MOH that took part in the questionnaire have concerns with the medicine situation, the question at this stage is why nothing has been done about it.

This state of dissatisfaction with the medicines situation might demonstrates a level of lack of communication between the clinical staff who are dealing with health and medicine affairs directly and the administrative staff at Kuwait MOH, as they are not capable of resolving the concerns causing the clinical staff to be unsatisfied with the current medicine situation. This attitude was apparent when 60% thought that there is room for improvements within the MOH Medicine regulations. This response is demonstrated in the following bar-chart and table 24.

Table 4.13: How well regulated the MS			
		Frequency	**Percent**
Valid	Not well regulated	19	22.9
	Appropriately regulated	5	6.0
	Room for improvement	50	60.2
	No Comment	9	10.8
	Total	83	100.0

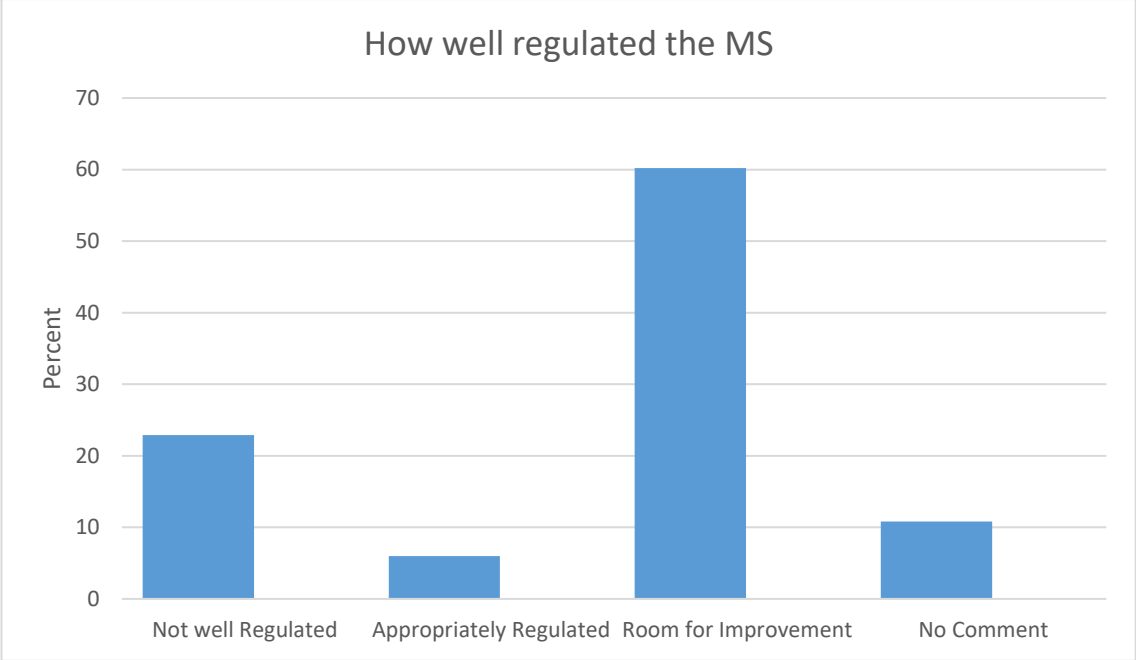


Figure 4.11: Bar chart to demonstrate the participant's thoughts on the regulatory statues of the medicine situation at Kuwait MOH.

From the results obtained above it is clear that there are very few number of health professionals who are involved directly with medicines that think the medicine situation is well regulated. This outcome complements the previous results; it's obvious that the medicine situation is inadequate in the view of the healthcare providers that took part in the survey. Such situation might cause the staff to be distressed and work in a very sub-standard environment. The outcome of working in poor work environment could be an unsatisfactory healthcare regardless of the strength of the human resources, if the regulations and policies are not robust; the strength of the workers is inadequate to provide a suitable level of healthcare.

At this point a serious system of organisation might be useful, and supporting the healthcare system with strong regulations to ensure its endurance and operation could be of added value to enhance the overall health of the population.

When the EML concept was explained to the participants, almost all the participants strongly agreed on the establishment of an EML in the State of Kuwait. Only 4.8% had no strong feelings towards EML.

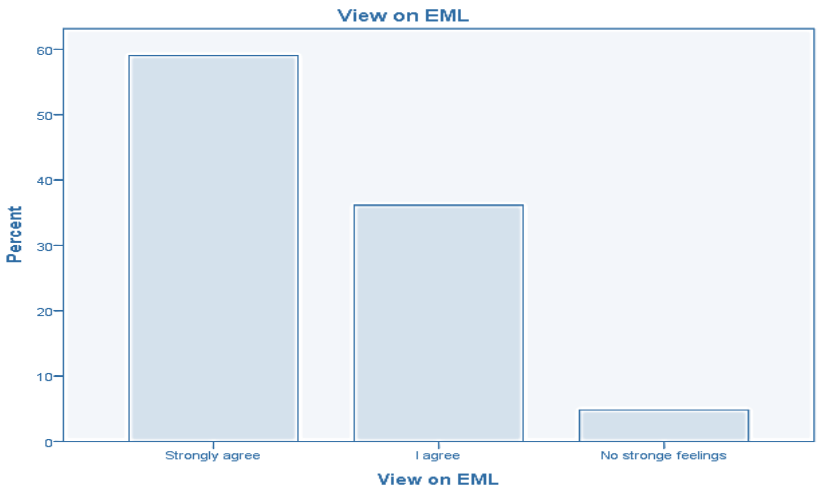


Figure 4.12: Respondents Views on the EML concept Bar-Chart

Table 4.14: View on EML			
		Frequency	Percent
Valid	Strongly agree	49	59.0
	I agree	30	36.1
	No strong feelings	4	4.8
	Total	83	100.0

A cross-tabulation was carried out to compare the experience level against the views on EML, the reason for this cross-comparison is to establish a connection between the level of experience and the desire to innovate, it is believed that the more experienced healthcare providers would be more aware of the healthcare system and the medicine situation and might be able to provide a meaningful data to help in understanding the medicine situation efficiency at the state of Kuwait, the outcome of this cross-comparison is demonstrated in the following table and Bar Chart.

Table 4.15: Work experience against View on EML Cross-tabulation					
			View on EML		
			Strongly agree	I agree	No strong feelings
Work experience	1-5 Years	Count	10	8	3
		% within View on EML	20.4%	26.7%	75.0%
	6-10 Years	Count	20	10	1
		% within View on EML	40.8%	33.3%	25.0%
	over 11 years	Count	19	12	0
		% within View on EML	38.8%	40.0%	0.0%
Total		Count	49	30	4

Figure 4.13: Cross-comparative bar-chart for the views of EML against work Experience

The Cross-Comparison demonstrated that the less experienced health professionals are the ones who couldn't form a complete opinion towards the EML concept, whereas the group that served over 11 years made an opinion that either agreed or strongly agreed with the concept, this response can be justified by the fact that the more experienced healthcare providers are more aware of the medicine situation in Kuwait Healthcare public sector and can form a solid opinion, in the other hand the less experienced staff might be less aware

and don’t have a broader awareness of the medicine system, and that might explain the reason behind their response.

The next part of the questionnaire tried to view what the healthcare providers thoughts on generics, because EML encourages the utilisation of high quality generic medicines, the prescribers were asked in what situations would they be willing to prescribe generic medicines to their patients. The responses varied, each prescriber saw it from a different perspective, the outcome of the thoughts on generics were described on the following table and bar-chart.

Table 4.16: Generic prescribing (Dr Only)

		Frequency	Percent
Valid	Always	3	3.6
	If patient happy to take it	10	12.0
	If no brand	13	15.7
	sometime	1	1.2
	Total	27	32.5
Missing	999	56	67.5
Total		83	100.0

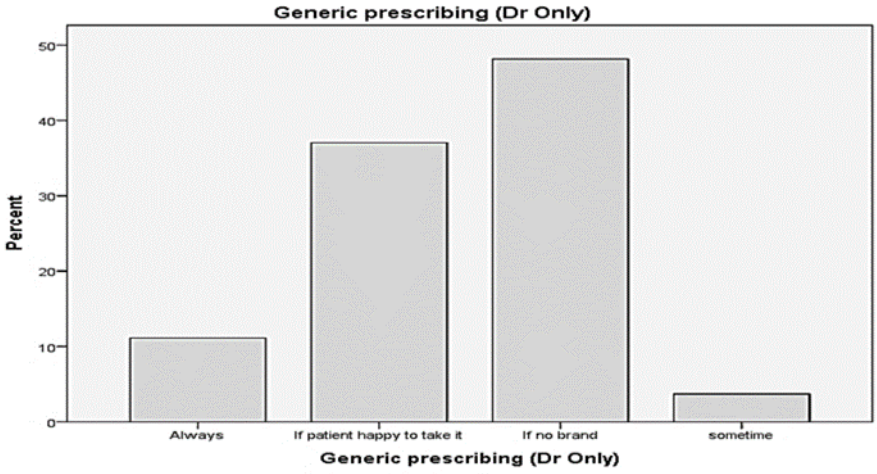


Figure 4.14: Participants prescribing protocol in relation to Generic medicines.

The responses to the question were that the prescriber that took part in the questionnaire, will only prescribe generics based on patient choice and if there were lack of the branded medicines; and thus these are the two main situations in which the prescriber would recommend generic medicines to its patients.

This type of prescribing practice demonstrates that even doctors are not fully agreeing on prescribing generics and this needs further investigation to understand their rationale for such practice. But generally speaking, generics has a bad reputation among patients who think that generics are of less quality than branded medicines; this assumption is based on the fact that the cost of generics are a lot less than branded medicines.

Generic medicines are defined by WHO as '*a pharmaceutical product, usually intended to be interchangeable with an innovator product, that is manufactured without a licence from the innovator company and marketed after the expiry date of the patent or other exclusive rights*' (WHO.2016). Basically, the generic medicines have the same active ingredient as the branded medicines, but have different product names and different inactive ingredients, the results have different excipients. The generic medicines could have a different texture, appearance, taste or even smell from the branded equivalent. Such changes make patients doubt the quality, and they refuse to comply with the treatment. This doubt of generic medicine quality might be due to lack of proper patient education; it's an important matter that needs to be considered when implementing EML. Otherwise, patients will refuse the choices of essential medicines on the EML and that would lead to failure in the implementation process.

Looking at the results of the questionnaire, it's clear that there is almost an agreement on the dissatisfaction level with the medicine supply system among the health professions who are directly involved with the medicine supply cycle. The health professions appear to think that there is an immediate need for reregulating the medicine supply system. Almost all the participants thought that the implementation of an EML would have a positive influence to

the medicine supply system. One finding, which should raises concerns, was the fact that generic prescribing is not very popular and it would only be carried out in the case of a lack of branded medicines.

The next segment will include the findings of the Standard Treatment Guidelines Questionnaire. STGs are a very important tool that supports the essential medicines selection process, for this reason it's important to learn the available guidelines.

4.6 Standard Treatment Guidelines (STGs) Questionnaire

The questionnaire was designed to view the STGs being currently followed at Kuwait healthcare facilities. This is prepared because the medicine selection on EML should conform to STGs being followed. For this part of the research work, 90 medical doctors were surveyed, the study included multi-centres, varied almost evenly, between primary, secondary and tertiary healthcare facilities. Almost half of the participating doctors had 6-10 years' work experience.

The following table represents the distribution of the questionnaire participants according to their work place.

Table 4.17: healthcare facility type		**Frequency**	**Percent**
Valid	primary healthcare facility	26	28.9
	Secondary healthcare facility	30	33.3
	Tertiary Healthcare Facility	34	37.8
	Total	90	100.0

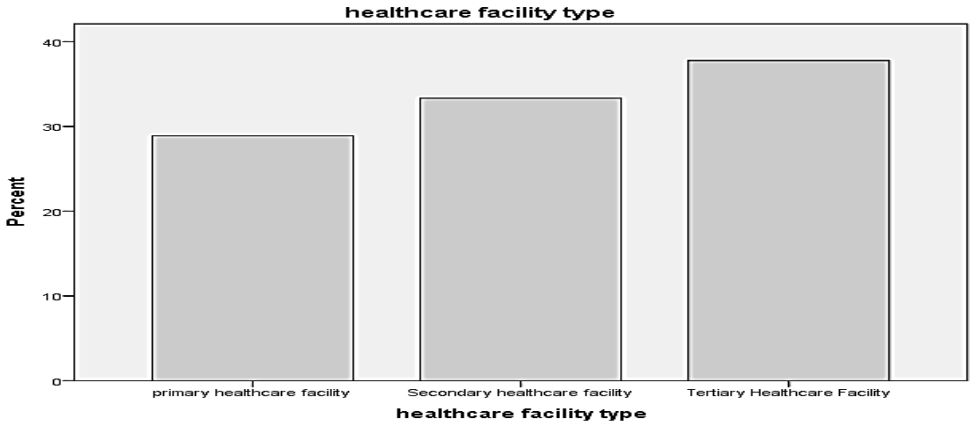


Figure 4.15: The distribution of the participants over the three level of healthcare at Kuwait MOH

Most of the participants had 6-10 years' experience and the rest are divided into those with less than 5 years and over 11 years. The following table and chart represents the distribution of the participants.

Table 4.18: Work experience in years		**Frequency**	**Percent**
Valid	1-5 Years	22	24.4
	6-10 Years	42	46.7
	11 Years	26	28.9
	Total	90	100.0

Figure 4.16: participants work experience distribution

The awareness level of the existence of STGs was 85%, very high, but it's very worrying that there are a few doctors who were unsure or had a slight awareness of the available STGs, the question at this stage is what are the treatment protocol the unaware doctors are following and how are they treating the patients.

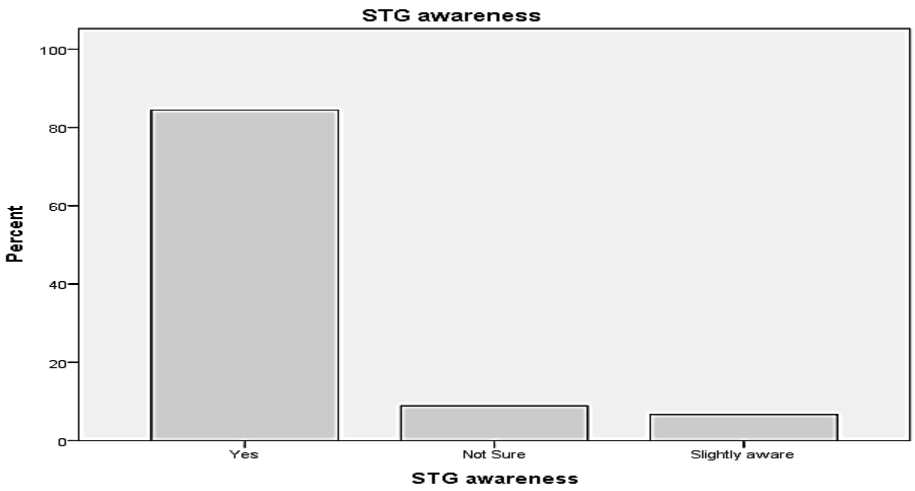


Figure 4.17: the participant's level of awareness with the existing of STG

Table 4.19: STG awareness					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	76	84.4	84.4	84.4
	Not Sure	8	8.9	8.9	93.3
	Slightly aware	6	6.7	6.7	100.0
	Total	90	100.0	100.0	

Only 40% of the respondents were using local national STG, the rest varied on the STG following on their prescribing regimen. A large percentage used international STG, and 13% used their own designed STG.

Table 4.20: The type of STG being followed by the participants			
		Frequency	Percent
Valid	Local	40	44.4
	Own	12	13.3
	International	34	37.8
	Total	86	95.6
Missing	9999	4	4.4
Total		90	100.0

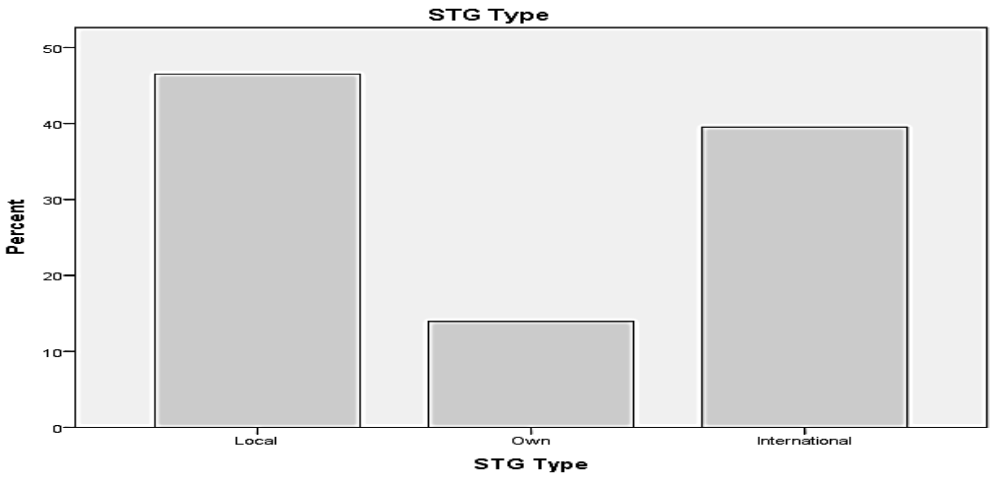


Figure 4.18: Participants STG type

Prescribers using their own designed STGs, and not following a well-designhned treatment regimen is considered as a lack of Good Prescribing Practice, because prescribing needs to adhere to well documented guidelines to allow a standardised treatment throughout the healthcare system. This way prescribers will have a clear idea of how patients are being treated and other doctors can follow other patients without disturbing there treatment regimen, this leads to improved therapeutic skills.

It is believed that having national Standard Treatment Guidelines will allow better medicine utilisation and will lead to better procurement practice, this is the case because all parties that are involved in procurement and prescribing will be able to predict what medicines are required and the amount that need to be available to cover the healthcare requirements. On the other hand, lack of uniformity in the guidelines being followed, will result in undesirable patient confusion, conflict in deciding how to proceed, loss of doctor reliability in patient views, morbidity due to adverse drug reactions, and all this would result in patient lack of compliances; waste of resources is another point which needs to be considered, because inappropriate medicine use causes medicine waste. An important example of misuse of medicines is antimicrobial resistance, due to over use or basically mixed use of multiple antimicrobials.

Another important finding is that only 26% of respondants were aware of other colleagues STG, the rest had no idea or were unsure; the results are described below. Such situation might lead to inability of other prescribers to

cooperate in patient treatment, and might be unable to help patients other than their own.

Table 4.21: Similarity of the STG with colleagues			
		Frequency	Percent
Valid	Yes	26	28.9
	No	4	4.4
	Maybe	50	55.6
	Not Sure	10	11.1
	Total	90	100.0

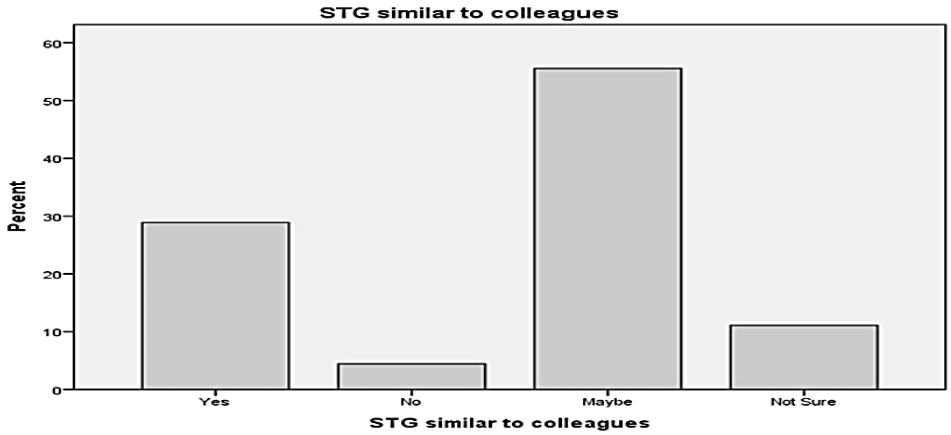


Figure 4.19: The awareness level of the respondents with their peers STG

Respondents explained the choices in various ways, half of them are using the official STG of the healthcare centre, but 22% were using STG from their training abroad. This situation might be inappropriate because, Kuwait has a different health profile than others and the genetic disposition of Kuwait ethnicity not necessarily similar to other countries. For this reason using STG from other countries might be unsuitable and maybe harmful.

Table 4.22: Reason for using this particular STG		**Frequency**	**Percent**
Valid	Knowledge from previous University training	8	8.9
	Conveyed from previous training at different country	22	24.4
	Official guideline of healthcare centre	50	55.6
	instructed by	6	6.7

	previous colleague		
	Others	4	4.4

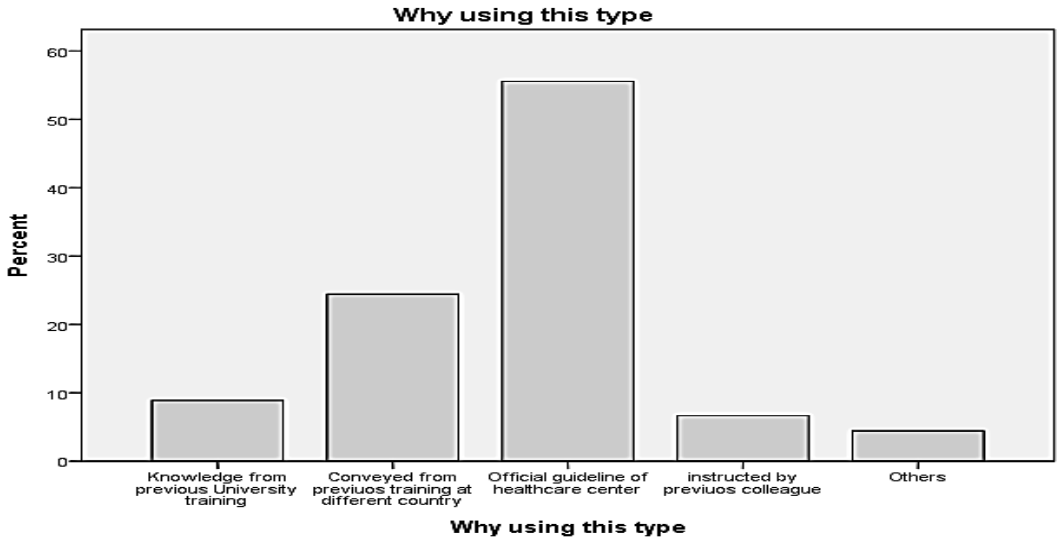


Figure 4.20: the participant's reason for following a particular STG

A cross-comparison between the work experience and the type of STGs being used was conducted to view any significant finding in relation to how the new prescribers would react towards treatment options and compare it with the way the more experienced prescribers handle prescribing.

The following table and Bar-Char demonstrate the relation.

Table 4.23: Work experience in years Vs STG Type Cross-tabulation					
Count					
		STG Type			Total
		Local	Own	International	
Work experience in years	1-5 Years	14	0	6	20
	6-10 Years	22	10	10	42
	11 Years	4	2	18	24
Total		40	12	34	86

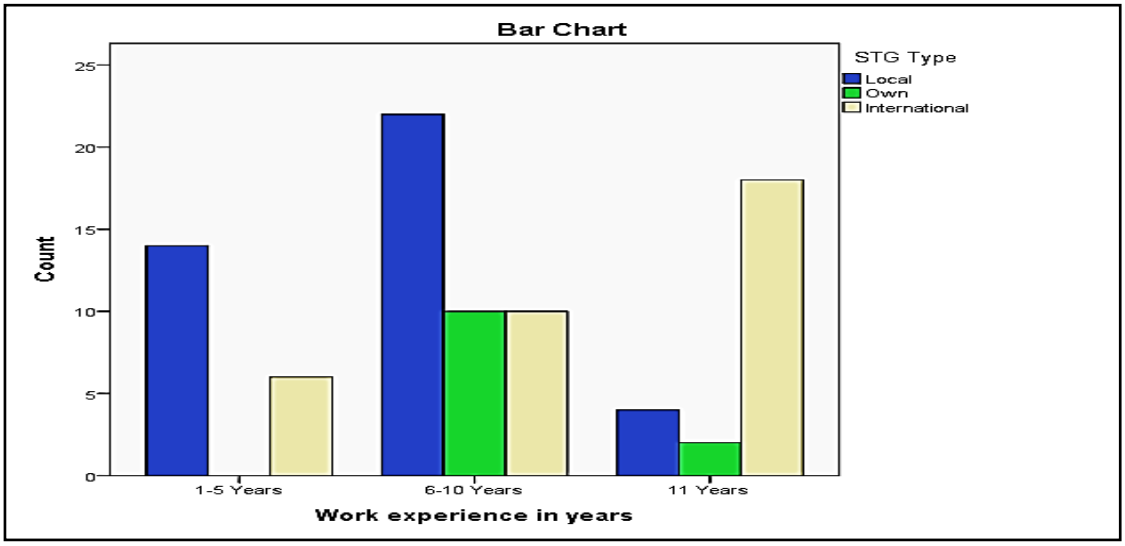


Figure 4.21: Work experience in years Vs STG Type Cross-comparison

The comparison of the work experience and the type of STGs being used revealed that the new doctors are more committed to the local guidelines, but some are using the guidelines they learned during their international training, and none of them are coming up with own guidelines. It makes sense, especially that doctors with less than 5 years' experience, might lack the skill to design their own STG. What is noticeable is the fact that more experienced doctors follow the international STG, this can be explained by the fact that the more experienced doctors go to a lot of international conferences and international workshops. This may be one reason for them adopting an international approach in prescribing treatments.

The most used STGs are the local STGs and the Canadian Guidelines; there are two reasons for such high usage of the Canadian Guidelines. The first one is that most doctors get their speciality training in Canada, and that's why they use the Canadian Guidelines. The second reason is because Kuwait MOH is trying to start a standardisation protocol by adopting the Canadian process and has a Canadian team of healthcare experts in Kuwait MOH to change the current policies at The MOH. Table 34, sum up all the different types of STG followed by the participants.

Table 4.24: STG types being followed by the respondents

STG	Number	%
NICE	2	4.4
Internet search	1	2.2
International Guidelines	6	13.3
Canadian STG	11	24.4
American Medical Association Web Site	5	11.1
Evidence-Based Practice	2	4.4
Uptodate.com	1	2.2
Maudsley Prescribing Guidelines "*The Maudsley Prescribing Guidelines (also known by the abbreviation MPG) is a referenced prescribing guideline for psychotropic drugs*"	1	2.2
Kuwaiti Board Training	4	8.8
Healthcare facility Own STG	12	26.6

Another important point that needs to be recognised is the fact that there is no monitoring to STG being used, no follow-up, and it's been observed that the existing guidelines are based on the current and earlier practice rather than evidence based; there isn't any kind of update or even evaluation for the currently used STGs.

Chapter Five

Discussion

Recommendations and Policy Implications

5.0 Introduction

This chapter contains the findings discussion, in the context of exiting research on the concept of the Essential Medicines and the suitability of this concept to Kuwait's public sector healthcare situation. Based on the findings of the study, the practicality and appropriateness of the medicine policy that it is consisted mainly of the Essential Medicine List and the Standard Treatment Guidelines will be demonstrated. This chapter will answer the research questions based on the outcome of the studies conducted, it will justify the approach used to answer the research questions and it will demonstrate the limitation of the approach.

Thesis discussions conventionally put the findings that have been experimentally determined, in perspective with the findings made by the previous researcher. For this particular research, it is not possible to do this comparison. The major reason for this is because there are no previous works in the topic relating to Kuwait, and if we like to compare the findings of this research with other studies conducted to other countries that have similar health profiles to Kuwait, that is again not a possibility. The reason is that Kuwait's situation is unique; it's certainly a high-income country where the GDP (PPP) per capita is USD 70686 (ranks 5th). It's human development index is high (0.816) and ranked 47th. However, it does not appear on the many lists that state the developed nations.

Kuwait has a place on the World Bank's high income countries list, but neither on the lists of the International Monetary Fund, Development Assistance Committee nor the Newsweek's World's Best Countries (20, with intensive access to resources and has great availability of health technologies which are comparable to advanced countries, but Kuwait on the other hand, is similar to limited resource countries in terms of organisation, some type of health corruption and serious bureaucracy difficulties. Consequently, Kuwait's unique health system has no direct parallels against which to compare.

What has been done in relation to this research work was to compare various Kuwait health aspects with several countries, each aspect compared with a different country's situation.

This research work aims to answer the research questions systematically by the way of the proposition emerged from four different methods of study, each stage of the research answered one of the research questions, however, the research work outcomes will give directions on the recommendations needed to be considered if the concept of Essential Medicines gets implemented at the health public sector in the State of Kuwait.

5.1 Research Question One and Two

"What is an Essential Medicine List and why do countries need it?"

"What are the characteristics of an effective EML Programme?"

The first two research questions seek to investigate the WHO concept of EML, how it's defined, the method of implementation, the update of the EML over the years, the percentage of adapting the EML by the member countries, and the suitability of the EML to high-income countries. This information is important to establish whether the EML is suited to Kuwait, or if it's only valid for low income countries. But first it's important to understand its objectives and aims to be fully aware of its implication.

The general focus of the WHO Model List of Essential Medicines is medicine quality and access, the two terms are interchangeable, no patient should get access to medicine unless it's of established quality, otherwise, the concept fails to achieve its target which is the general wellbeing of the population.

Another focus for EML is cost, this term is relevant to each country's available funds, and how much any government is able to spend on medicines and the available health reimbursements schemes. In a country like Kuwait, the funds are available but the process of utilising the funds efficiently and transparently is not clearly defined. Medicines are prescribed to patients in the public sector free of charge, and a three month supply is provided and in some cases a six month supply is given, another form of medicines drainage were

found in the visiting visa patients, that only pay a small amount of ten Kuwaiti dinar and get prescribed medicines with a very high cost.

This policy of medicine prescribing causes drainage to the medicine resources, especially the six month supply of medicines, where patients are stopped from using the current treatment regimen and moved to a new regime, the massive supply of medicines will be disposed and wasted, and this is a massive drainage of medicines.

If Kuwait public health system followed a more organised prescribing, procurement concept, such approach might reflect positively on the overall health and the might even deliver a system of control over cost. Kuwait requires a system that will be able to deliver a solution to the massive number of medicines on the CMS; this massive number gave rise to high cost, medicines procurement challenges, it might go further to include a system that will enhance the prescribing protocol and such system would eventually provide better health.

One proposition is to adopt the concept established by the WHO of Essential Medicine List; the WHO EML is suggested by the WHO to member countries to help them to deliver some type of an organisation to the medicine situation in each country, the work of the WHO is not a mandatory and the WHO does not impose its adaptation, it is merely a guide to aid country in their medicines related innovation. The work of the WHO was directed towards countries with limit access to resources and countries with issues with sanitation and have difficulties with access of clean water, for this reason the WHO Model EM included a number of medicines related to infectious diseases, in the more resourceful countries the health requirements are different, the diseases profile are more directed towards life style and modern none-communicable diseases, for this reason the WHO Model List of Essential Medicines are not a suitable form to be adopted in the exact layout by the higher income countries. The medicine choices on any newly designed nEML is required to be complying with the health situation, the affordability level of the population and the country adopting the concept, and the availability of suitable healthcare facilities to provide the required health level using the selected Essential Medicines.

The selection process of medicines on the WHO Model EML is based on the WHO Standard Treatment Guidelines, it's considered a good practice to have STG to follow and the STG needs to be suitable to country's health needs and medicine capabilities.

The WHO Model EML has gone through rigorous scrutiny over the years; it started as a list of drugs aimed at limited income countries, but over the years the List direction changed and more higher income countries has adopted the concept in different forms, the expanding number of countries adopting the Model EML concept resulted in different disease profile and different health requirements, for this reason the Model EML has evolved and several changes has taken places, the revised Model EML included medicines that are more expensive and due to the availability of the world Pharmacovigilance programmes and the widespread of quality medicine information, the selection of these medicines moved from experimental based choices onto more of post-market evidence based choices.

The updating of the list was crucial to keep up with the advancements in medicine technologies and the change of diseases patterns. The list currently includes more expensive medicines, which are considered to be cost-effective, such as antiretroviral medicines.

The major indication of EML concept success is demonstrated in the WHO Model EML continuance since 1977; it has been adopted by many international none-profitable organisations. Another evidence that might be considered as a type of success confirmation of the Model EML is the fact that over time a large number of countries, with various standards of livings, are adopting the EML concept and adjusting it to suit each country's health requirements. The keyword at this stage is adjustment; the EML concept adaptation requires alteration to suits the national health requirements of each country, the medicines on each national EML vary and for a national EML to succeed it needs to be tailored to each country's health needs, financial resources and the available Standard Treatment Guidelines.

The general timeline of the WHO Model EML started in 1970 as general idea and the WHO expert advisory Committee met in 1975 and published a

model List of EML in 1977 with 208 medicines. The list got updated every two years, in 1981 the WHO established the WHO Action Programme on Essential Medicines to support the EML concept, until 2009 there were over 156 countries with an EML. Looking at the map below, it demonstrates countries from different levels of income and each country is adopting the list for different reasons. The map demonstrates as well, that most of the countries adopted the EML concept in less than 5 years; it's an indication of the recent popularity of the EML concept. Many high-income countries are seeing useful utilisation to the EML, not only in terms of cost reduction and enhancing medicine access but also in providing more medicine and distribution organisation and control over the medicine list.

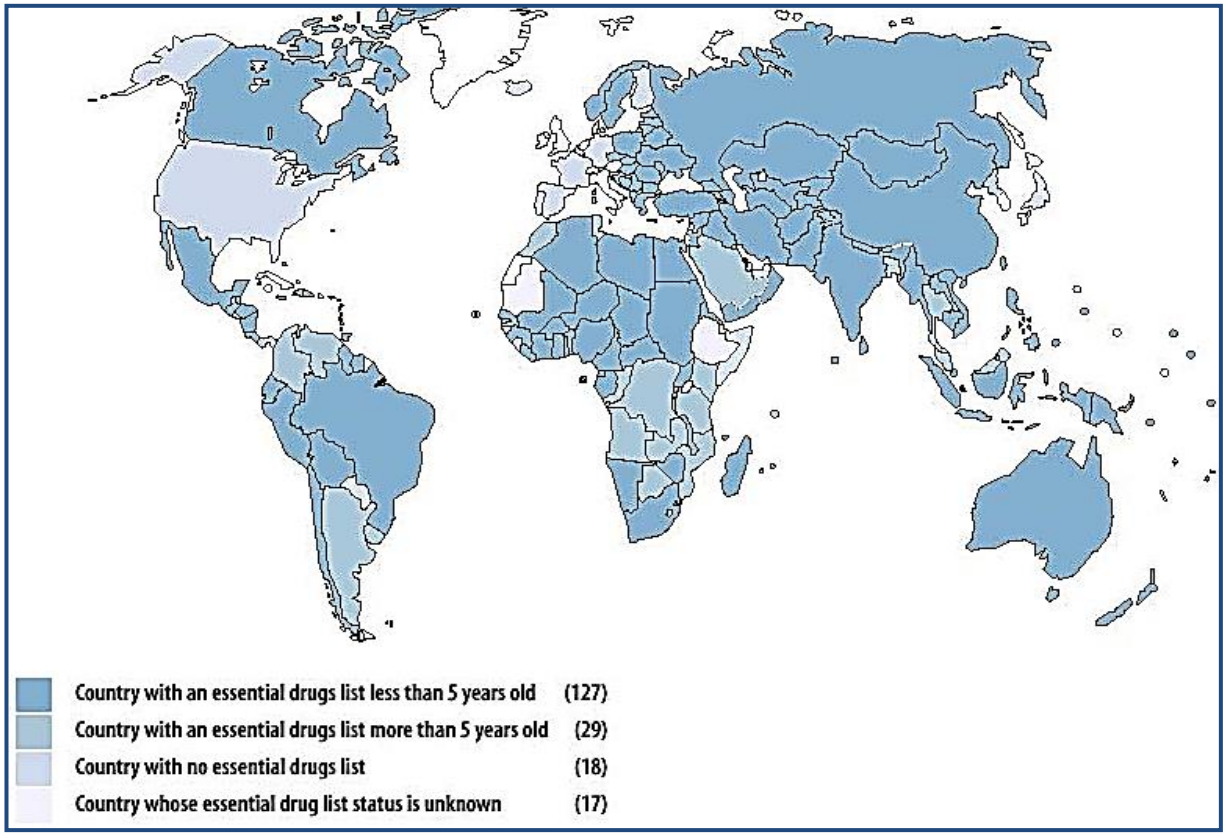


Figure 5.1: Countries with an official selective list for training, supply, reimbursement. Some countries have state/provincial lists instead of or in addition to national lists. Source: WHO, World Drug Situation Survey, 1999

The WHO provided support to countries to start their own policy of Essential Medicines to 113, of which 22 benefited from comprehensive programmes (WHO, 2016).

The following figure 32, demonstrates the percentage of the countries benefiting from the WHO assistance, the figure also demonstrates that there are 22 countries benefiting from full support of the WHO to start medicine policy and EML, other countries are getting more of a technical support.

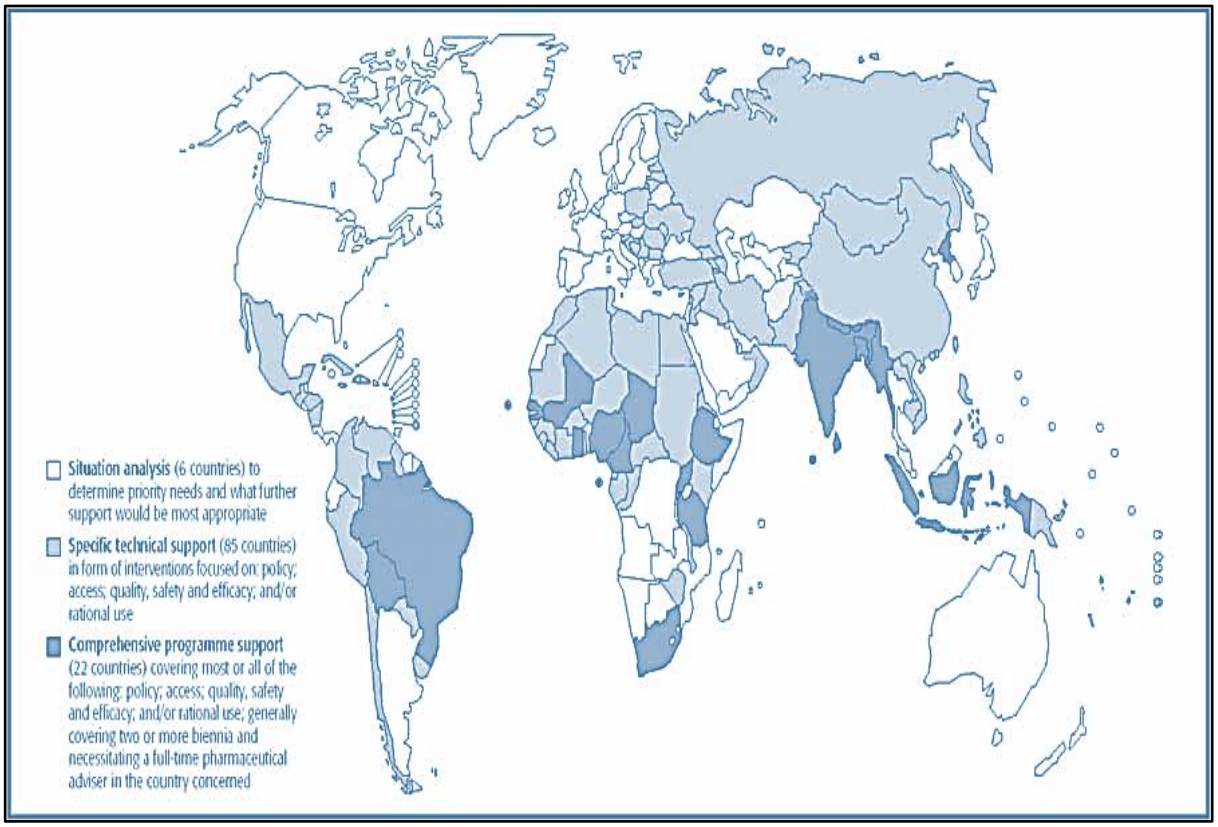


Figure 5.2: the distribution of countries benefiting from the help of the WHO in designing their nEML

At the turn of the century, the EML became more beneficial to wider range of countries. The EML became valuable to the industrialised countries, because the medicine expenditure shows unsustainable growth of 12-18% per year, emphasising need for prioritisation and rational medicine selection (WHO Annual Report, 2003).

The EML has provided other practical usage beside access to quality affordable medicine, an additional importance of the EML concept was found in helping the public sector in medicine procurement and distribution, it can be seen as a monitoring system for medicine availability and pricing, enhances the in-service training of healthcare providers, enhances medicine transparency and decreases antibiotic resistance when rational drug use is followed.

From the information gained, it's apparent that the EML started as a means to control cost and quality, but as time passed, the Model EML progressed and had further role as an instrument to enhance several aspects of the medicine situation in many countries, regardless of the income level.

Overall the EML based on the number of countries adopting it has become universally accepted, it became widely utilised in low and middle income countries and in recent years it's been widely implemented in the high-income countries. The EML had several other uses other than enhancement in medicine access and cost control, it's been used in health provider training, in medicine supply and reimbursement, enhancing procurements and medicine quality control.

Generally, the EML can be considered a success in meeting the proposed objectives set by the WHO Expert Advisory Committee and might even went further to be a valuable tool in medicine control and Rational Drug Use and the general enhancement of the overall health.

The overall framework of an effective and successful EML, is to design a list of a reasonable and controllable number of medicines, the medicines on the list need to follow the cost-effectiveness concept carefully, the selection process is required to be carefully suited to the country's health requirements and the process of implementation needs to be transparent and frequently monitored and updated.

5.2 Research Questions Three

"To what extent have other countries succeeded in their implementation of an EML?"

The third research question aims to gain experience from the process of implementing EML by other countries, it's to give a perception of what to expect and what to evade if the list became available in Kuwait.

To answer the question, two studies were conducted, one was conducted at an international level, studying 5 countries with various income

levels, out of the five countries studied, two have a high income namely; Norway and Australia.

Norway has the highest income level in the world; it's similar to Kuwait in-relation to the fact that patient expectations are high, and Norway is considered to have one of the highest healthcare expenditures in the world. The spending has grown in Norway more than any other OECD country and this is demonstrated in figure 33.

The following table demonstrates how much is being spent by Norway on health.

Table 5.1: Norway Health Expenditure Statistics

	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
% from the Government total budget	9.38	8.97	8.46	8.04	8.20	8.11	9.25	9.07	8.94	8.89

Health care expenditure by financing agent sourced from Eurostat: Statistics Explained. Last update: 11-05-2015

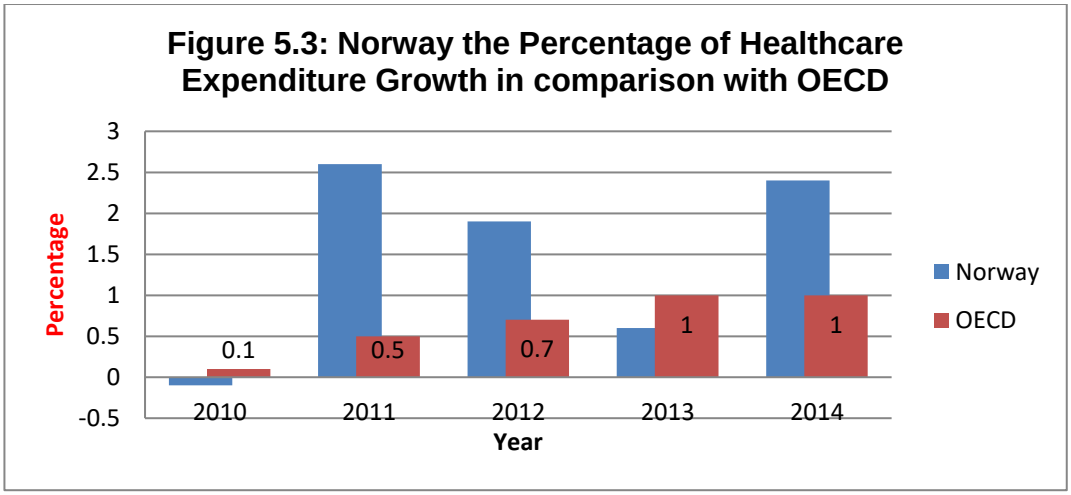


Chart sourced from: OECD Health Statistics 2015

In 2013, Norway had a lower expenditure than the rest of the OECD countries; this is because it adopted a system to lower pharmaceutical expenditure. They adopted a system of long-term care and increased the spending on that by 30% (OEDC Health Statistics, 2015). It can be deducted from this attempt by the Norwegian healthcare services, that if the medicines

budget get condensed and the money get forwarded to another preventive care it might have a deficit effect on the total healthcare budget.

The bar-chart demonstrate an increase in 2014 of the Health expenditure in Norway, reviewing the studies conducted by the OECD Reviews of Health Care Quality, there appears to be broad consensus across stakeholders over the direction of the health system, even when this entails significant challenges or adjustments, for example there has generally been agreement over the direction taken by the Coordination Reform. However, beyond this broad consensus there is a lack of consistent meaningful engagement between key stakeholders (for example, discussion and negotiation between GPs, municipalities, hospitals, mental health services) which is an obstacle to the successful implementation of some impressive aspirations for improvement, particularly around increasing co-ordination (OECD, 2014).

The Norwegian Health Services director was considered as the EML concept builder, his aim was not only to control cost but also enhance rational drug use. Although Norway is a high-income country, it still found it important to practice control over the increasing medicine budget. Norway faced oppositions from the Pharmaceutical industry and has been accused of restricting the free trade of medicines.

Such objection is understandable; the pharmaceutical industry would prefer to have the total freedom over selling newer medicines and more expensive medicines and from a business point of view, would like to have more control over medicine prices. This is not happening otherwise the Norwegian Health services would be faced with a serious medicine budget issue and this is the major reason for adopting EML by the Norwegian Health services.

The second-high income country that adopted EML is Australia, it had the lowest cost of medicines in the world in the past, but in recent years the prices went up. The Australian Health services adopted the concept of EML and made the system of reimbursement based on it.

The concept of basing the reimbursements of medicines on the EML is commendable, but the actual application of it is not accomplished, it's been found out, through a study conducted by Duong (2015) that the decision makers at the Australian Health Services have a confused perception of what is considered an essential medicine. The stakeholders mixed up the essential medicines with the reimbursed medicines, and thought that the selection of the essential medicines is based on consumer demand. This is could be an indication that the concept of EML has not been fully explained to the whole of healthcare providers and for it to be operating efficiently, a suitable education programme might be useful to provide a suitable level of EML implementation and efficient utilisation of the concept.

Rational drug use is a major criterion on the objectives of Australia for adopting EML, and the second objective is to control and maintain a suitable pharmaceutical industry.

The third country, with many attempts to start an EML, is India; it's a lower middle income country, it is one of the first countries to start EML in the third world countries, with several failed efforts. The main issues with the medicine situation in India were the unverified medicine quality, lack of price control, weak pharmaceutical regulations and weak enforcement of the regulations, problems with irrational drug use and a major problem with what is known as the witch doctors and the untrained pharmacists.

India attempted lots of policies to try and resolve the issues, but all failed. The failure can be related to lack of focus on the Essential Medicines, and the procurement didn't get based on EML. Another reason is that the medicine selection didn't get based on the actual health needs but the major reason for the failure of all attempts, was due to the strong opposition by the very powerful pharmaceutical industry in India.

Such a situation requires a strong transparent government that would not get influenced by incentives from the rich pharmaceutical industry, but this is difficult for a country with extremely limited resources, referring back to Kuwait such a situation shouldn't be applied but unfortunately similar situations do

happen in Kuwait. The pharmaceutical industry in Kuwait is very limited and most of the medicines get imported, but there are a lot of incentives given to the healthcare providers to ensure that a specific supplier wins the bid of a bid tender. This might be considered as a form of lack of transparency or an ignorant form of medicine corruption that is draining the health budget.

It's a serious matter and if not fought and controlled, no policy would be strong enough to endure such corruption and lack of transparency, the term corruption is a strong term to be stated but it comes in various level and the type that is present in Kuwait Healthcare Services is an invisible type and most of the Healthcare providers are unaware of it as being a form of medicine corruption, it might be presented at a very small level, by posting a specific medicines posters at any healthcare facility that would be viewed by patients all the time and the result would gain preference over peer medicines, another form of medicines corruption is accepting incentives from pharmaceutical suppliers in return to prescribe a specific medicines, this form of practice might seem harmless but it can be alarming and requires careful deliberation, because prescribing is required to be based on medicine post market evidence of effectiveness and quality rather than advertisement and enforcing the medicines.

In relation to Kuwait, it was ranked 66 in 2012 at the transparency rank, but in the latest 2015 ranking, Kuwait had moved up to be at 55, which is a good improvement considering the current unstable political situation in the region (U.S. Dept. of Commerce, 2015) (Transparency International, 2016).

The following table demonstrates how Kuwait ranked in the Corruption Perception Index from 2012 until 2015.

Table 5.2: Kuwait ranked in the Corruption Perception Index from 2012 until 2015.

Year	**2015 Score**	**2014 Score**	**2013 Score**	**2012 Score**
Rank	49	44	43	44

Sourced from Transparency International Official website, 2016

The Transparency International defines the rank which has been used as '*the score indicates the perceived level of public sector corruption on a scale of 0 (highly corrupt) to 100 (very clean). A country's rank indicates its position relative to the other countries in the index. This year's index includes 168 countries and territories*.' (Transparency International. 2016).

Kuwait comes just a few ranks before Oman, but is the most corrupted country among the rest of the GCC countries, if this is the case that might reflect negatively on the process of innovation, which might be faced with serious hindrances, generally, careful transparent approaches are required to any innovative process including health related and medicines innovations.

This score shouldn't be taken lightly, especially with a country that has a great deal of funds which can bring the country to a very high standard of living, if the corruption gets controlled. Further to this fact, Kuwait is considered a literacy-free country, because according to the World Bank Adult Literacy rate, it states that 96% of Kuwaitis are able to read and write (World Bank, 2016). Considering these two facts the corruption level in Kuwait should be less and measures are needed to contain the situation.

Since Pharmaceutical products take a large portion of the health sector budget, it's vulnerable to corruption. Corruption can be defined in the general way as being '*the abuse of public office for private gain*' (World Bank. 2016). Pharmaceutical corruption is more specific and can exist in several forms; major forms of pharmaceutical corruption found in questionable medicine quality, lack of medicine access; some forms found in the Kuwait health sector, that is considered as corruption when refereeing to the definition of medicine corruption, but the healthcare providers in Kuwait are unaware of it as being so. One type is the over prescribing of medicines to some patients, another form is some medicines go missing, or even queue-jumping which is an occurring event, and the last corruption form is sadly practiced by many levels of authorities in Kuwait public sector.

Transparency International suggests that, all members of the community, at all levels, have an important role in corruption control, it suggests that

accountability from all health professionals and administrators need to be demanded (Transparency Int. 2016).

The U.S Energy Information Administration, rank Kuwait as holding 6% of the world reserves in oil, and it estimates that Kuwait will remain as one of the world's top oil producers (U.S. Energy Info. Adm. 2016). As a step to improve the country and to explore other resources other than oil, the Kuwait Parliament approved a USD 110 Billion National Development Plan; part of this fund is allocated to improve the health sector (Kuwait MOH, 2016).

In Seri-Lanka, the situation was different; the Seri-Lankan public healthcare wanted to adopt the concept but failed because of the changing health political climate. Such situation is common in the developing countries and as a result of this political climate change, the high level management changes frequently and decisions made by previous managers stop and new ones get put in place until the next group of high ranking decision makers joins and so on. Such scenarios are found in Kuwait, new Ministers of health are frequently appointed, and the decision made by the previous Minister gets stopped by the next appointed Minister.

This is a major point and needs to be closely deliberated, if the concept of EML gets implemented in Kuwait, there should be strong regulations that wouldn't be affected by the changing of managements, and the regulations need to be stated to enforce EML use and implementation regardless of who is in charge of the ministry at that point.

A good scheme to do so is by assigning a specific committee of qualified health professionals and there interests should be clearly declared, transparency must be applied at all levels. The committee members should not be chosen based on favouritism. The members should not receive any financial or none-financial incentives by participating in the committee, the committee members are required to be independent decision makers and be fully aware of the concept and the selection process. If any of the above doesn't get fulfilled the concept will face the same fate as all the previous third world countries, a inadequate none-operational concept.

Kuwait might face a similar situation as Bangladesh when it tried to attempt the EML concept. Since the seventies Bangladesh made several attempts but all failed and the main reason was bureaucracy and bias, the selection committee members were pharmacists and the actual health needs were unknown by the appointed expert committee members.

One attempt of Bangladesh to implement EML was based on the international selection criteria of medicines and this failed as well, the reason is that each country has unique health needs and should not copy other countries' EML, it will not satisfy the current needs of the country. This fact needs to be considered when the concept of EML gets implemented in Kuwait.

Therefore, the EML concept is a good tool to control budget and provide quality relevant medicines to the population, but what is equally as important as the concept itself is full knowledge of it, its process of implementing, involving all stakeholders and educating them on the gains of the concept.

Opposition is expected, but care needs to be practiced to understand their reasons and try to bring them on board, full careful explanations of the EML need to be introduced to all opposing parties, once this is done, their views for opposing the implementation of the EML need to be stated, preferably in writing, once this is done, each concern needs to deliberated and answered. Enforcing a concept with a lot of opposition will cause its failure, it is important to take as many supporters as possible to ensure utilisation and adherence.

At an Arabic level, there are 12 Arabic countries with EML, the standard of living varies among the Arab countries, some have limited resources others are undergoing serious political and war situations which is stopping all types of innovation and bringing the country to a very bad era.

The Arabic world has gone through lots of changes since the start of what is known internationally as 'the Arabic Spring', terminology widely refused by the Arabic community. Simply because this term indicates the start of a good era, but the Arabic spring caused a lot of distress and chaos. This has been apparent in the health services and medicine supply in countries undergoing conflict. It also caused a social and economic inequity, lack of accountability

and the elevation of corruption level. The request of reforms by the civilians was faced with the use of force and that is very clear in countries like Syria, Bahrain and Iraq. The disturbed Arabic political climate has created what is known by political scientists as, fractionalisation, it's a term used to describe a situation when countries undergo division in their own lands. Powell-Jackson *et al* (2011) suggests that countries undergoing fractionalisation have reduced access to healthcare among other services (Powell-Jackson *et al*, 2011).

Going back to the research question of whether other countries have succeeded in there adaptation of the concept, the answer is not so straight forward, the system seems to be in place, many efforts have been attempted to ensure its continuity but it's not clear if it's actually totally operational.

It's apparent that having a list doesn't necessary mean that the EML is being employed efficiently, and it is proposed to consider the utilisation efficiency level when adopting the concept, it is proposed that the concept requires serious commitment by all the decision makers to make the concept work. It needs a suitable timeframe and effort for it to be effective.

Having a well-designed EML, even if it's appropriate to the needs of the country doesn't necessarily guarantee its success. Many factors need to be taken on-board, transparency is key, corruption control is very important, declare of interest when selecting specific medicines is important, educating the health providers with the concept is an important component. But these are not all the efforts that need to be carried forward, it's very important to get the healthcare recipients involved as well, this is achievable, by providing a suitable level of education in the process, be transparent, get them involved and gain insight to their thoughts on the matter.

There is a general belief among healthcare recipients and some of the healthcare providers that the generic medicines are of weak quality and not effective. These thoughts have been the result of lower quality generics, for this reason it's important to re-evaluate the quality of existing generic medicine and only accept those with suitable quality. The healthcare recipients might benefit of a suitable level of education with generics; this will help in regaining the trust

with the generic medicines and make generic medicine more acceptable to patients. The process of educating the public can be done in several means, it can be visual in the form of television advertisements, internet awareness campaigns, flyers and leaflets handed out to people in public and in health regions. It can be done through an awareness programme at the local primary healthcare centres and local community centres.

The major issues that have been observed with the EML relating to the Arabic countries are the change of the health requirements due to the disturbed political climate. There are a lot of injuries and deformities due to war and protests that cause increased demands on emergency medicines, pain control therapy and surgery related medicines. This is evident in places like Syria, Iraq, Yemen, and Libya. The result of such situations is that the essential medicines cannot be accessed and the EML is not being updated to fit the new health changes. The Arabic uprising has diverted the efforts from focusing on health and medicine access to trying to control the disorder that is increasing in the region.

When comparing the various EML of countries with various standards of living, the outcome of this comparison was very interesting. Some countries adopted the exact WHO Model List of Essential Medicines, where other countries have used it as a guideline and made appropriate changes to suit their own health circumstances. Adopting an EML of another country is a very major misconduct in the implementation of the EML, simply because different countries have different health requirements. This situation was found in Tunisia; the Tunisian EML was published with the aid of three international organisations, the WHO, the Italian Technical Cooperation and the Belgium Drug Directory, the results of such cooperation is an EML that is relatively similar to the Belgium List. It's clear that Belgium has different access to resources and different health needs. Such adaptation of the EML by Tunisia is destined for failure, because one of the major criteria of an EML is to be relevant to the health needs of the country and the relevance to the standard of living of each country.

Another important observation was the fact that many Arabic countries adopted the EML a while ago but completely ignored the concept and not fully continued with the updating until very recent years. This was the case with Egypt, the Egyptian's first EML were published in 1998, then no updates until 2006. It's a very long period to leave an EML unrevised. In Bahrain the first EML were published in 2009 and seven years later no updates until now. In the Kingdom of Saudi Arabia, the situation was different, the SA MOH had multiple committees taking part in medicine selection of the first EML, but when the Saudi Arabian FDA staff were contacted for clarification for the process of utilising the SA EML, the response was that they had heard about it but they are not aware of its utilisation and they have no access to it. This is a total disappointment to the EML, the list needs to be accessible by all healthcare providers and it needs to be utilised in all aspects of pharmaceutical service works.

When examining the different lists closely, it was apparent that the concept of cost-effectiveness is relative and is country-specific, what is considered costly in one country is not necessary costly in another. The rules used to examine the cost-effectiveness of particular medicines are different from one country to another.

The list varies depending on various factors, it can differ in accordance with the Standard Treatment Guidelines used by a particular country, it can change due to different health requirements, and the selection of medicines can vary depending on the practicality of obtaining a specific medicine, whether it requires special handling, or special storage or even special transportation. Another consideration when selecting medicines is to obviously consider cost and quality and consider how it is possible to maintain the quality of medicine during the whole shelf-life and during handling and storage.

Overall, having an EML doesn't necessarily guarantee its success, the list needs to be adopted correctly, following suitable guidelines with the assistance of the international guidelines but not a total adaptation of the international guidelines, the list needs to comply with the national Standard Treatments Guidelines to ensure its relevance to the health profile and disease

burdens of each country. The cost-effectiveness concept needs to be related closely and deliberated carefully to suite the available health funds, the expert committee members need to be chosen carefully and be independent decision makers that don't follow any specific organisation or have any type of interest in the medicine selection. The selection of medicine needs to be based on post-market evidence of quality and efficacy, for this reason a strong pharmacovigilance programme is urgently required to be started in the Arabic region and connecting it with the international pharmacovigilance resources is proposed to increase its efficiency.

In terms of generic medicines, it would be considered as good practice to re-examine generics' quality, and re-license them, then a good process of education for the healthcare providers and recipients with generics concept and its benefits might help in accepting the generics perception.

Opposition is expected with any new changes and reforms, the EML faced opposition from various sources, the doctors found it restrictive and patients found it limiting, therefore, it's very important to educate both parties. A related and suitable educational program is needed to explain the EML concept and the benefits of it should be considered when the concept is about to be launched.

The other form of opposition is found through the strong pharmaceutical industry and the medicine wholesalers, they are the main force of opposition, because they are the majority stakeholders that will lose a lot when the medicine situation gets organised. Ignoring such strong stakeholders is not a good practice, they need to be involved and faced with the reality of the implementation and adaptation of the EML concept, the incentives they usually giveaway to healthcare providers should be stopped, reduced to a minimum or have an organised method to deal with such practice.

The relationship between the pharmaceutical industry and the healthcare providers needs to have a form of control as well, any member of the medicine selection committee that have a direct or indirect interest with any kind of medicine should either abstain from providing an opinion on the matter of his/her interest or maybe be completely replaced by someone with no interest.

The list has gone underutilised by many countries, it's been found that having a well thought and well-designed EML doesn't necessarily ensure its effective implementation and usage. Many countries have made the efforts of planning and providing a suitable EML but the list failed to achieve its objectives, simply because there weren't any forms of regulation to enforcing its usage. For this reason, it is proposed that having a strong ministerial act might give strength to the implementation and utilisation of the EML, it is proposed that if the new regulation to enforce the utilisation of EML solid enough, it might be sturdy enough to endure the frequently changing political climates at the Ministry of Health in a third world country situation.

4.3 Research Questions Four

The last research question that has been investigated in this research is as follows:

"What are the contextual factors in Kuwait which would assist or hinder effective implementation of EML?"

The fourth research question was aimed to investigate what is available as health policies at Kuwait MOH in relation to the pharmaceutical sector. It aimed to find out whether these policies have been effectively implemented or was not so successful; it aimed to find out what is the continuous effect of the available medicine policies, and how these policies have been dealt with.

The question was answered through several interviews conducted with senior managers at Kuwait MOH, head of departments at Kuwait FDA and Kuwait University, Faculty of Pharmacy.

The outcome of the interview revealed that there were several attempts by the staff of Kuwait FDA to start several medicine related policies, but unfortunately, none of them were completed, and one of these is still paused and waiting further instructions.

The process of adopting any new policy is not well thought of, and the instructions are not clear. The problem as mentioned by Dr Wahede, Associate Dean, at the Faculty of Pharmacy at Kuwait University, is that the MOH in Kuwait deals with any policy as an administrative task rather than a scientific

based work, or a pharmaceutical based work. What is meant by this statement is that when a policy needs to be implemented, the committee meets and thinks of it in a rigid administrative form, by issuing all the relevant circular, that sometimes goes by the Minister of Health and other times it doesn't, thinking it's an internal pharmaceutical affair and no need to get any ministerial level approval. In such situations the policy gets diffused and paused. This obviously time consuming, wastes valuable health resources and further strains on the budget. This is the case because when any decision made when starting a policy, the assigned staff moves completely to that policy and stops doing any other tasks, and since the policy undergoing implementations doesn't have any clear instructions on what to do, the staff involved get paid for not doing anything and that's a form of masked unemployment and consequently drains the budget.

Another form of wasting MOH budget is found in the process of sending the assigned staff to training courses and workshops which cost money and not employing the experiences gained from their training effectively and productively.

It's been observed that there is a power struggle between the ministry of health pharmaceutical staff and the Kuwait Pharmaceutical Association. The power struggle was detected when Kuwait FDA tried to start the Kuwait Drug Index, at the same time, Kuwait Pharmaceutical Association came up with an edition called '100 Common Drugs' and are having an updated version published soon titled '200 Common Drugs'. The publication had 8 pharmacists working on it, the information was basically copied from the British National formulary, NICE, and Electronic Medical Compendium. The book was aimed to be a manual for new graduates to assist them in dispensing and can be used as a quick reference. The ranking and categorising of the book was based on the information gained from Kuwait MOH. The manual is a good attempt to organise information provided to the pharmacists, but it did not go through any monitoring nor revision, and the accuracy and validity of the information is not demonstrated.

There were no guidelines followed when the manual was being prepared. This situation indicates the fact that MOH managers and the pharmacists in general, are unaware of the fact that there are international tools to help them with policy planning and health innovations.

One explanation for such a situation is that managerial level are awarded based on the length of time at the job and not based on qualification, capability and excellency in the job. This method of allocating managers and team leaders has two sides to it, it is good in regards to the fact that everyone gets an equal chance to get promoted, but the down side to it, is that spending longer years in a job doesn't guarantee efficiency and competency in managing the team or the department. This process requires restructuring and extremely delicate deliberation.

The continuous attempts to innovate is a demonstration of the effort that needed to be in Kuwait a long time ago, but even when attempts were made to start a new policy, it failed and the interest diverted to another policy. This situation is apparent in several aspects at Kuwait MOH, but in relation to this research it has been demonstrated when an attempt was made to launch the Kuwait Drug Index which is similar to what is known internationally as the National Medicine Formulary, then the interest moved towards the establishment of the Pharmacovigilance Department. Although both of the policies are strongly needed and should be adopted, both are not being executed, the concept is available on papers but the actual operational part of it is not in place. This is another form of time and resource wastage.

Other than the lack of knowledge, bureaucracy is another reason for the absence of advancement and innovation in the pharmaceutical sector at the State of Kuwait. This statement came after analysing the responses gained from interviewing high ranking and managerial level staff members, they were all happy with the concept of EML, but they were all concerned that it will face other policies destiny and it will fade away.

The interviews gave a good insight into Kuwait's current medicine situation, and it gave an indication on how the system works in the MOH, the general understanding of the concept was available, and all agreed that it will

be of added value to the medicine situation in Kuwait MOH. There were however, concerns with the actual process of implementation, none of respondents were encouraged or had a positive view of the success of the implementation process, the concerns varied from the fact that the EML can work if it's implemented in a transparent manner; it's an obvious requirement, lack of transparency will destine the EML to failure, as happened with several developing countries. Another obstacle is the process of gaining official approval which is time consuming and exhausting, and that is a reason why some policies get implemented without the official governmental approval and then get stopped or dismissed. All are valid concerns and need to be considered when the EML gets implemented.

The positive impact of the EML concept on the MOH Budget was recognised by the participants, it will enhance the control of the escalating medicine budget, but it needs to be considered that the actual percentage of the medicine budget from the total MOH budget has not changed over the years. It's the actual MOH budget that increased, therefore, the MOH needs a general concept of redistributing the allocated budget and try to invest in preventive care rather than the current system of curative care.

The survey conducted revealed the lack of organisation in terms of prescribing, the physicians don't have a specific national protocol when prescribing to patients, each physician uses their own protocol based on experience, previous training or own initiative. Such a situation is not acceptable and causes a lot of confusions, especially among patients, this is the case because diseases can be treated in several ways using several regimen and sometimes the physicians can't necessarily remember each regime used with each patient. In the case of Kuwait, doctors are using several European, American and British treatment protocols that vary in the types of medicine that is available in each country, and the result of this none-unified treatment guideline is a more extensive list of medicines and consequently a bigger medicine budget.

The availability of STGs is of added value at several levels, the healthcare providers will have a standard guide on prescribing, it enables the

healthcare providers to provide quality care, the prescribers will be more aware of the prescribed medicines, since they follow well thought out guidelines that include suitable and quality essential medicines.

There is a positive impact to manage funds more efficiently, especially when there is previous knowledge of the required medicine, having a suitable STGs will enhance procurement and will help in better management for the medicine supply cycle. But the main beneficiary are patients, the STGs will provide the best option of treatment patients should receive, all patients at all levels of healthcare will be treated similarly, having a known STGs will enhance the availability of medicines, and consequently better patient compliances and satisfaction.

The second survey in regards to the views of the healthcare providers on Kuwait's medicine situation were interesting, all demonstrated the desire to improve the system, a large number are unhappy with the current system, and all are very happy with the concept of EML and would like to see it get implemented. Such thoughts and responses are clear indications that the healthcare providers are keen to innovate and would like to see the medicine situation in Kuwait improve and get transformed to a better and more advanced situation.

Another point worth considering is the fact that physicians don't prefer to prescribe generic medicines and this reflected on patient's opinion of generic medicines. The general thought is that generic medicines are of less quality and manufactured in a lower standard than the branded medicines. The general misconception has been demonstrated through the health carer recipients, partly because there are some local generics in Kuwait that are not up to the required standards and patients did not have a pleasant experience using them, and partly because some patients mix the concept of generic medicines with counterfeit medicines. Therefore, it's very important to educate the patients of the concept of generic medicines and retest and re-establish the quality of already available generics.

Quality generic medicines can be considered as a useful tool to enhance medicine access and control funds, according to Chief Pharmacist Fahad Al-

Qatan, Special Medicines Department Manager at the CMS. Generic medicine arrives faster to the CMS, the suppliers do not complicate the process of purchasing and delivery, therefore, generics are not only less expensive, but also save time in procurement as well. Therefore, it's important to establish trust in generic medicines and make them more acceptable to patients, because the impact on health and the general wellbeing is good, and it will enhance medicine supply and control the funds.

This is one of the points that needs attention if the concept of EML gets implemented at Kuwait MOH, there are several conceptual factors that might hinder the implementation of any policy in Kuwait, and those factors will affect the process of implementing EML as well. Such general conceptual factors are competition among the high level management to claim the new innovative ideas as their own, lack of commitment and loss of interest is present to any new plan, the inexperience of the assigned staff to carry forward the new policy and the results of being unable to implement the new policy effectively, a large number of healthcare providers lack the awareness of the international guidelines and the results are placing a policy that is weak and inefficient.

One major and frequently occurring factor that might hinder the process of innovation is the long excessively complicated administrative procedure that needs to be followed every time an improvement or change needs to occur. This bureaucracy is a major hindering factor and causes loss of motivation and eventually lose of the policy.

In relation to the Kuwait situation, the main and most apparent reason for the slow innovation process in Kuwait MOH is the fear of losing personal incentives if any change occurs, therefore, higher level staff are always vigilant to any new concept and make sure it won't affect them personally in an undesirable manner.

The mentioned conceptual factors that might hinder the effective implementation of the EML at the state of Kuwait needs to be carefully approached and resolved before attempting the concept of EML implementation. If that has not been considered, the EML will face a similar fate to all the previous policies that have been attempted previously and failed.

5.4 Recommendations for the Kuwaiti Government

The following recommendations are formulated for the process of implementing EML, and are considered important factors in the process of EML launch.

The intensive list of medicine that is available at Kuwait MOH, needs to be revised and updated and only medicines that are prescribed frequently need to be included. Anything less than frequently prescribed, needs to be considered as an orphan medicine and specific rules should be applied to provide it.

The problem of the drainage of medicine to none-resident patients' needs to be emphasised and very restricting and clear policies need to be in place.

The open access of consultants, to order any medicine, is proposed to go through reregulating and it would be more beneficial if it get limited to extremely special cases.

Transparency is key; it should be practiced at all health aspects and especially in the medicine supply. If transparency gets implemented effectively, it's proposed that the medicine corruption level might drop and this could enhance the public confidence in the pharmaceutical sector.

Educating the healthcare providers and healthcare recipients is very important; all should be included and considered, education programmes can start at a school level up to the public in the local clinics. Workshops and training programmes should be conducted at all levels to healthcare providers and recipients. The programmes need to be provided by suitable and knowledgeable staff, and preferable no financial incentives to be given to eliminate the competition of the people who are after financial gain rather than sharing knowledge and educating the public.

Policy makers and the decision makers in Kuwait MOH have a duty to examine and assess the current level of government bureaucratic procedures towards any health innovation ideas or plans.

In more medicine, related work, several medicine related policies can be started in Kuwait such as Pharmacovigilance, Standard Treatments Guidelines, Health Providers and Recipient Education Programmes and a major change to the management structure would be beneficial to be considered.

Standard Treatment Guidelines are almost none-existing, STG are an important part in the medicine selection process in the EML and therefore, serious work needs to be done in planning and making Kuwait-specific STG. This is achievable by establishing a STG committee, which will develop a comprehensive plan for the guidelines. The committee will select the format, recruit contributors, and reviewers to establish the STG. When deciding on the most appropriate treatment option, it is important to consider using few medicines, bearing in mind the cost-effectiveness of the choices being made, base the selection on the Essential Medicines, and clearly indicate what is the first, second, and third line therapy is, and the treatment course should be clearly described. It is worthwhile to refer to the WHO guidelines when planning the local STG. Once the STG are decided, it is advisable to pilot it and test it before publishing it. Once it's ready, the STG needs to be implemented in an appropriate mode, continuous staff training is vital, and regular monitoring is essential as well, plus the guidelines should be regularly revised and updated.

There is a major need to organise the health sector at the state of Kuwait in general and the Pharmaceutical sector in particular, it might be useful to include a more knowledgeable staff and give them further suitable responsibilities to perform and innovate. The Pharmaceutical infrastructure needs to be reconstructed, this can only be achieved by having well-qualified staff and experts design an information sharing and reporting system, at a national level and connect it with the available international resources, and having a transparent and experienced advisory committee.

The inflated MOH general budget and the inflated medicine budget, needs to be prioritised, plans and policies that have been used by other countries, to provide control over these countries' budget, need to be considered and adopted, the EML concept has proven over time its effectiveness as a tool to organise funds and enhance medicine access.

The EML can only fulfil its objectives if it's been implemented transparently, it should follow the international guideline but should not be an exact version of the international EML or any other country's national EML. The government needs to create an awareness of the concept of Essential Medicines among health recipients and providers, the MOH should consider reregulating the registration of new medicines and adopt a suitable system to ensure the quality of medicines that is available.

The Kuwait national EML can have a different structure to the WHO Model EML, a common practice observed by other countries is to combine the STG with the EML as a single document or include the STG in the comments section of some essential medicines.

Several general factors would affect the implementation process, these factors need to be deliberated in advance to avoid future obstacles or even the termination of the process of implementation of EML. The factors are the available pricing policy, access of essential medicines, reimbursement scenario, government initiatives in supporting implementation, patent and licensing scenario and healthcare infrastructure. Some of these factors have no impact in Kuwait because they are not available; such as the reimbursement scheme, other factors are very important and require careful deliberation. The pricing of medicine is usually the main concern to some countries, in Kuwait, pricing is not a major one and this might be one of the reasons for the inflated budget of pharmaceuticals in Kuwait, therefore it's important to adopt a suitable system for pricing and maybe follow the footsteps of some middle-income countries and have a price ceiling for high-priced medicines.

Shortage of some medicines might be present in Kuwait MOH, this is the case because of the intensive list of medicines that need to be procured at all

the time. If the focus moved from attempting to provide all of the over 7000 medicines on the CMS list of medicines, and only focused on a more reasonable list of essential medicines, medicine access might be enhanced. This is not the only factor that needs to be considered, the government needs to support the concept of EML and provide sufficient planning but this won't be possible unless a serious restructuring of the pharmaceutical infrastructure occurs. It has been noticed in Kuwait a number of patients can't get access to certain medicines and end up buying from the private sector which will result in an increase in the out-of-pocket expenses; this could be the results of poor management or inefficient procurement process.

The entire above factor needs to be considered to be able to have an operational and useful EML that would enhance the general health and control the inflated medicine budget.

5.5 Limitations of the Study

One main limitation to this study is the lack of similar published studies, the other limitation is the inaccessibility of Kuwait health resources and the lack of secondary data relating to any aspects of Kuwait health.

This study is a first of its kind in regards to Kuwait, the methodology employed is specifically designed to this particular study, unless an exact study should be attempted, this study can't be generalised nor transferred, and this is another limitation to this study.

5.6 Recommendations for Future Research

The study suggested a number of directions for future research, it's important to research the health corruption level and the level of actual transparency at Kuwait Ministry of Health. It would be of added value to study the reason behind the current bureaucracy at the government sector and what are the appropriate methods to evade it.

Since there are no actual studies in regards to Kuwait health needs and there is no published data to support any further research, it's proposed to research the reason for the lack of appropriate medicine related research in relation to Kuwait.

5.7 Final Comments

Through the research results, it's been found that the Essential Medicine List is a valuable tool to perform medicine control and organise the medicine situation in a given healthcare centre regardless of the budget limitation and the amount of the available resources, providing there is an appropriate utilisation of the concept.

It's been found, through research conducted, that having a well-planned and well thought EML doesn't necessarily ensure its efficient utilisation. The EML needs to be supported by regulatory and human support, as well as having a good monitoring and updating system, it's important as well to have a

transparent process of medicine selection and medicine selection committee members with no interest in the selected medicines.

EML is an efficient tool in enhancing medicine access in limited resource countries, but it went further with its significance to include further benefits to high income countries in terms of budget control, medicine control, good procurement practice, medicine corruption control, reimbursement scheme and many other values depending on each country's situation.

The survey conducted in Kuwait MOH revealed the eagerness of the healthcare providers towards health and medicine innovation, as they see new international policies as a suitable method for employing control and organisation at the MOH in Kuwait. The concerns were that such innovations might be faced with opposition from the stakeholders who might lose interest if the current organisational culture changes, such situations need careful deliberation and each opposing suggestion or thought needs to be explained and clarified before moving forward.

The survey demonstrated the lack of trust in generic medicine quality and efficiency, it's important at this stage to restore the confidence back to generic medicines and explain the actual meaning of generics to the whole population through various types of health educational programmes.

The EML can be of added value to the Kuwait medicine situation if implemented, handled correctly and appropriately. The EML implementation process in Kuwait needs to follow very careful footsteps, the health needs of Kuwait needs to be clearly established, the selection of medicines needs to be carefully executed, the process of introducing the EML to the healthcare recipients and providers needs to be carefully attempted and a suitable plan needs to be in place for the overall implementation process.

List of References

1. A B Sturm, Michael; Siegfried, Nikolaus (June 2005). Regional Monetary Integration in the Member States of the Gulf Cooperation Council (PDF). Frankfurt am Main, Germany: European Central Bank. ISSN 1725-6534. Occasional Paper Series, No. (31).
2. A glossary of technical terms on the economics and finance of health services (1998) World Health Organization, Regional Office for Europe. Available at: http://www.euro.who.int/__data/assets/pdf_file/0014/102173/E69927.pdf
3. Abed, George T. (1 April 2003). The GCC Monetary Union: Some Considerations for the Exchange Rate Regime (PDF). Washington DC, USA: International Monetary Fund (IMF). ISSN 1934-7073. Working Paper No. 03/66.
4. Abel-Smith, Brian (1977) Minimum Adequate Levels of Personal Health Care, in Issues in Health Care Policy, ed. John Mckinlay, A Milbank Reader 3, New York
5. Acocella, N. and Di Bartolomeo, G. and Piacquadio, P.G. (2009) '*Conflict of interest, (implicit) coalitions and Nash policy games*', in: '*Economics Letters*', 105: 303-305
6. Alesina A, La Ferrara E (2005) Ethnic diversity and economic performance. *J Econ Lit*; **43:** 762–800.
7. Alkelya M, Alenezi MG, Alsultan MM, AlJeraisy M (2015) The Characteristics of Pharmacy and Therapeutic Committees in Saudi Hospitals. Presentation. *ISPOR International Society for Pharmacoeconomic and Outcomes Research 20th Annual International Meeting*. Philadelphia, PA, USA.
8. Alsharif, Asma (2011) "Gulf bloc to consider Jordan, Morocco membership". Reuters. Retrieved 2011-05-10.
9. Ananda Jayasinghe (2004) Is there hope for South Asia? Sri Lanka's Health System: It the most cost-effective in the world ?. BMJ 2004; 328:777
10. Application Form for the 17th Expert Committee on the Selection and Use of Essential Medicines (2009) Geneva: World Health Organization.

11. Arthur Miller (2016) New Bahrain Centre for Syrian refugees. *Dilmun-Time.* Bahrain accessible: http://www.dilmun-times.com/?p=39895
12. Asch DA, Hershey JC (1995) Why Some Health Policies Don't Make Sense at the Bedside. Ann Intern Med.; 122:846-850.
13. Australian Government, Department of health and Ageing (2000) National Medicine Policy. Commonwealth of Australia.
14. Australian Government. The people of Australia. Australia's Multicultural Policy; (2011) Australian Government, Department of Social Services. Australia.
15. Australian Pharmaceutical Manufacturing Association (2000) Facts Book 1999-2000. North Sydney: Australian Pharmaceutical Manufacturing Association.
16. Bahrain MOH. (2004) Bahrain Health statistics, Ministry of Health 2003–2004 Kingdom of Bahrain Government publication.
17. Banerjee, D (1973) Population Planning in India – National and Foreign Priorities, CSMCH, JNU, New Delhi.
18. Bankowski Z, Dunne JF (eds) (1994) Drug surveillance: International co-operation past, present and future. Proceedings of the XXVIIth CIOMS Conference, Geneva, Switzerland 14-15 September 1993. CIOMS. pp13-21
19. Batliwala, Srilatha (1978) The Historical Development of Health Services in India, FRCH, Bombay.
20. Beiske, B (2007) Research Methods: Uses and Limitations of questionnaires, interviews and case studies, GRIN Verlag.
21. Bhore, Joseph (1946) Report of the Health Survey and Development Committee, Volume I to IV, Govt. of India, Delhi
22. Bibile, S (1977) *Case Studies in Transfer of Technology: Pharmaceutical Policies in Sri Lanka,* UNCTAD, Geneva, 1977, TD/B/C.6/21.
23. Bishai D (2007). "Does the level of infant mortality affect the rate of decline? Time series data from 21 countries". *Econ Hum Biol.* **5** (1): 74–81.
24. Britnell, Mark (2015) In Search of the Perfect Health System. London: Palgrave. p. 87.

25. Bryman, A. & Bell, E (2007) Planning a research project and formulating research questions. In: Business Research Methods. New York. Oxford University Press. P. 154.
26. Burnard, P. (1996). Writing Skills for Health Professionals. Nelson Thornes, Gloucester.
27. Business Dictionary (2014) BusinessDictionary. Accessible through: http://www.businessdictionary.com/definition/action-plan.html
28. C.I.A. Fact book (2014) https://www.cia.gov/library/publications/the-world-factbook/geos/in.html
29. Cacace, Mirella; Ettelt, Stefanie; Mays, Nicholas; Nolte, Ellen (2012) Assessing quality in cross-country comparisons of health care systems and policies: towards a set of generic quality criteria. European Health Policy Group, 20/21 September 2012 King's Fund, London.
30. Carson, D., Gilmore, A., Perry, C. & Gronhaug, K (2001) *Qualitative Marketing Research,* London, Sage.
31. Cees Kieft et al (2012) Kuwait Health Sector Report, Netherlands Embassy Kuwait & Bahrain.
32. Central Intelligence Agency (2013) the World Factbook. USA. Available from: https://www.cia.gov/library/publications/the-world-factbook/geos/ku.html
33. Ceri Phillips and Guy Thompson (2009) What is cost-effectiveness? Hayward Medical Communications, a division of Hayward Group Ltd.
34. Charles Clift (2013) The Role of the World Health Organization in the International System. Centre on Global Health Security Working Group Papers. Chatham House. London. United Kingdom.
35. Chris, Livesey (2006) The relationship between Positivism, interpretivism and sociological research methods. Revision: Sociological Methods. www.sociology.org.uk
36. CIA (2015) The World Factbook. USA https://www.cia.gov/library/publications/the-world-factbook/geos/mo.html
37. Clement FM, Harris A, Li J, Yong K, Lee KM, Manns BJ (2009) Using effectiveness and cost-effectiveness to make drug coverage decisions: A comparison of Britain, Australia, and Canada. *JAMA*.;302(13): 1437–43. doi: 10.1001/jama.2009.1409

38. Collins CD, Green AT, Newell JN (2002) The relationship between disease control strategies and health system development: the case of TB. Health Policy 2002; 62:141-160.
39. Commonwealth Department of Health and Aged Care (1999) *National medicines policy 2000*., Canberra: Commonwealth Department of Health and Aged Care.
40. Commonwealth Department of Health and Ageing (2002) *The national strategy for quality use of medicines*. Canberra: Commonwealth Department of Health and Ageing.
41. Connelly, L. M (2008) Pilot studies. Medsurg Nursing, 17(6), 411-2.
42. Cosmetics (1985) Devices and Drugs Act No. 27 of 1980', *Gazette of the Democratic Socialist Republic of Sri Lanka,* (Extraordinary), 2 December, 1985, 378/3. [Regulation governing the CDD Act.]
43. Crowther, D. & Lancaster, G (2008) "Research Methods: A Concise Introduction to Research in Management and Business Consultancy" Butterworth-Heinemann
44. D. Squires and C. Anderson (2015) U.S. Health Care from a Global Perspective: Spending, Use of Services, Prices, and Health in 13 Countries, The Commonwealth Fund.
45. David Morgan (2015) OECD Health statistics 2015. Country Note: How Does Health spending in NORWAY Compare? Accessible: https://www.oecd.org/els/health-systems/Country-Note-NORWAY-OECD-Health-Statistics-2015.pdf
46. De Vaus, David (2002) Surveys in Social Research, p5. Routledge, London,5th Edn.
47. Department for International Development (2004) Increasing access to essential medicines in the developing world: UK Government policy and plans. London, UK accessible through; (http://www.dfi d.gov.uk/Pubs/fi les/ accessmedicines.pdf, accessed 2 December 2007).
48. Department for International Development (2004) *Increasing access to essential medicines in the developing world: UK Government policy and plans*. London, (http://www.dfi d.gov.uk/Pubs/fi les/ accessmedicines.pdf, accessed 2 December 2007).

49. Department of Statistics (2006) Jordan in Figures 2006. Hashemite Kingdom of Jordan Government Publications. Amman. Jordan.
50. Department of Statistics (2006) Preliminary Estimates of the GDP for 2006. Hashemite Kingdom of Jordan Government Publications. Amman. Jordan.
51. Dept. of Statistics (2009) Jordan Population and Family Health Survey 2009, May 2010, Department of Statistics, Amman, Jordan.
52. Dhawan, R. e t al (1990) 'Whose interest? Independent India's patent law and policy', in *Conquest by Patent: On Patent Law and Policy,* occasional paper presented at the National Seminar on Patent Laws, National Working Group on Patent Laws, New Delhi, India.
53. Dr David Torstensson and Dr Meir Pugatch (2012) What Lies Within? Procurement processes and the risk of substandard medicines. Stockholm Network.
54. Dr Sneha Ambwani and Dr A. K. Mathur (no date) Rational Drug Use. Health Administrator Vol: XIX Number 1: 5-7. Jodhpur.
55. Drummond MF. (1992) Basing prescription drug payment on economic analysis: the case of Australia. Health Affairs; (11): pp191-6.
56. Duggal, Ravi and S Amin (1989) Cost of Health Care, Foundation for Research in Community Health, Bombay
57. Duong M, Moles RJ, Chaar B, Chen TF (2015) World Hospital Pharmacy Research Consortium (WHoPReC) Essential Medicines in a High Income Country: Essential to Whom? PLoS ONE 10 (12): e0143654. doi:10.1371/journal.pone.0143654
58. Elinor Bartle (2014) Shouldn't evidence be a part of decision-making? Selection of essential medicines in Tanzania is currently based more on experience and subjective criteria than on evidence. Department of Global Public Health And Primary Care. University of Bergen. Accessible: http://www.ncbi.nlm.nih.gov/pubmed/24416293
59. Elizabeth Roughead (2009) Australia's National Medicines Policy: Providing an Integrated Policy Platform for Pharmaceuticals. University of South Australia, Australia.
60. Essential medicines and health products (2006) The WHO Essential Medicines List (EML): 30th anniversary. WHO. Geneva. Switzerland.

61. Eurostat (2015) Statistic Explained. Healthcare expenditure statistics. Accessible through http://ec.europa.eu/eurostat/statisticsexplained/index.php/Healthcare_expenditure_statistics
62. Eva Ombaka (2009) Status of medicines procurement. *Am J Health-Syst Pharm*. 2009; 66(Suppl 3): S20-8
63. Expert Committee on Public Health Systems (1993) MoHFW, GOI, New Delhi
64. Federal Ministry of Health/WHO (2005) National Drug Policy. Abuja: federal Ministry of Health. Nigeria. Accessible through http://collections.infocollections.org/whocountry/collect/whocountry/pdf/s6865e/s6865e.pdf
65. Fernando Antezana and Xavier Seuba. (no date) Thirty Years of Essential Medicines: The Challenge. Farmamundi - Servicios Centrales en Valencia. Spain.
66. G. Walt, J. W. Harnmeijer (1992) “Formulating an essential drugs policy: WHO’s role”. In N. Kanji, A. Hardon, J.W. Harnmweijer, M. Mamdani & G. Walt (Eds.), *Drugs Policy in developing countries*. London: Zed Books. United Kingdom.
67. Gayatri R. Rao (2015) Rare Diseases at FDA: A Successful Year for Orphan Products. FDA Voice. U.S. Food and Drug Administration. USA. http://blogs.fda.gov/fdavoice/index.php/2015/02/rare-diseases-at-fda-a-successful-year-for-orphan-products/
68. GCC: Statistical Glance; (2010), Vol II, Information Centre- Statistical Dept., Riyadh
69. GCC; Statistics at Glance (2012) Information affairs sector, statistics department. Third edition. Riyadh. Kingdom of Saudi Arabia.
70. George, Alex et.al (1992) Household Health Expenditure in Madhya Pradesh, FRCH, Bombay
71. Giddens, A (1998) The third way: the renewal of social democracy. Cambridge: Polity Press.
72. Gold MR, Hurley R, Lake T, Ensor T, Berenson R.A. (1995) national survey of the arrangements managed-care plans made with physicians. N Engl J Med; (333): pp1678-83.

73. Grimshaw, J. Russell, IT. (1993) Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. Lancet; (342): pp1317-22
74. Guba, E. G., & Lincoln, Y. S. (1994) Competing paradigms in qualitative research. In N. K. Denzin & Y. S. Lincoln (Eds.), Handbook of qualitative research (pp. 105-117). Thousand Oaks, CA: Sage.
75. Gulf News staff report (2016) Oman's expatriate population rising rapidly. *Gulf News*. Oman. Accessible; http://gulfnews.com/news/gulf/oman/oman-s-expatriate-population-rising-rapidly-1.1843475
76. Handbook of resolutions and decisions of the World Health Assembly and Executive Board (1973) Vol 11948-1972. Geneva: World Health Organization, 1973. WHA16.36 Clinical and pharmacological Evaluation of Drugs.
77. Hans V Hogerzeil (2004) The concept of essential medicines: lessons for rich countries. *BMJ* 2004; 329:1169–72. Drugs and Medicines Policy, World Health Organization, Geneva, Switzerland.
78. Hans V Hogerzeil (2006) Essential Medicines and Human Rights: what can they learn from each other? *Bulletin of the World Health Organization*. 84 (5). Drugs and Medicines Policy. WHO. Geneva. Switzerland.
79. Hay, I. (2005) *Qualitative research methods in human geography* (2nd ed.). Oxford: Oxford University Press. United Kingdom.
80. Health Alliance International (2015) War & Public Health. Seattle. USA Accessible: http://www.healthallianceinternational.org/advocacy/war-and-public-health/
81. Health expenditure series (2013) Global Health Expenditure Database. Geneva, World Health Organization. (Latest updates are available on http://apps.who.int/nha/database/DataExplorerRegime.aspx).
82. Health Indicators for the GCC (2011). 15th edition. Riyadh. KSA.
83. Hertzog, M.A. (2008) Considerations in determining sample size for pilot studies. Research in Nursing & Health, 31,180-191.

84. Hill S, Yang A, Bero L (2012) Priority Medicines for Maternal and Child Health: A Global Survey of National Essential Medicines Lists. PLoS ONE 7(5): e38055. doi: 10.1371/journal.pone.0038055
85. Hill, R. (1998) What sample size is “enough” in internet survey research? Interpersonal Computing and Technology: An Electronic Journal for the 21st Century, 6(3-4).
86. Hoebert et al (2013) National Medicines Policies- review of the evolution and development processes. *Journal of Pharmaceutical Policy and Practice* 2013 6:5.
87. Hogerzeil HV et al. (1989) Impact of an essential drug programme on the availability and rational use of drugs. *Lancet*, 1989, 333:141–2.
88. Hudson, L., and Ozanne, J. (1988) Alternative Ways of Seeking Knowledge in Consumer Research. *Journal of Consumer Research*, 14(4), 508–521.
89. Ian McAuley (2014) Creating a better health system: lessons from Norway and Sweden. *The Conversation’s International Health Systems series.* United Kingdom, accessible: http://theconversation.com/creating-a-better-health-system-lessons-from-norway-and-sweden-30366
90. Ibrahim Al-Abbadi (2007) Health Care Equity Issues in Middle East. *presented during the Second Plenary Session, “Improving Equity of Access to Pharmaceutical Therapies in Europe, Middle East & Africa,“ at the ISPR 11th Annual European Congress, November 10, 2008, Athens, Greece)*
91. Ictsd.org. (2016). *EU-India FTA Will Not Hurt Generic Drug Makers: Minister | International Centre for Trade and Sustainable Development*. [online] Available at: http://www.ictsd.org/bridges-news/bridges/news/eu-india-fta-will-not-hurt-generic-drug-makers-minister [Accessed 28 Oct. 2016].
92. Implementation plan template (2015) www2.cdc.gov/cdcup/library/hhs_eplc/45%20-%20implementation%20plan/eplc_implementation_plan_template.doc
93. Isaac, S., & Michael, W. B. (1995) Handbook in research and evaluation. San Diego, CA: Educational and Industrial Testing Services.

94. Its Evolution and Lessons for the Future (1995) *The Journal of The Dag Hammarskjöld Foundation.*

95. J. D. Quick, H. V. Hogerzeil, G. Velasquez, L. Rägo (2002) “Twenty-five years of essential medicines”, *Bulletin of the World Health Organization*, vol. 80, nº 11, 2002, p. 913.

96. Jacobzone S (2000) *Pharmaceutical policies in OECD countries: reconciling social and industrial goals*. (Labour market and social policy – occasional papers No. 40). OECD, (DEELSA/ELSA/WD (2000)1) accessible through; (http://www.olis.oecd.org/OLIS/2000DOC.NSF/c5ce8ffa41835d64c125685d005300b0/c125685b0057c558c12568c400331a1e/$FILE/00075948.pdf, accessed 2 December 2014).

97. Jason Shafrin (2008) Health Care around the World: Norway, Healthcare Economist, Unbiased Analysis of Today's Healthcare Issues. Accessible: http://healthcare-economist.com/2008/04/18/health-care-around-the-world-norway/

98. Jordan Ministry of Health. (2006) Jordan Rational Drug List V1, 2006, Jordan

99. Julious, S. A. (2005) Sample size of 12 per group rule of thumb for a pilot study. Pharmaceutical Statistics, 4, 287-291.

100. K. Weerasuriya (1995) Development Dialogue 1995:1 • *A Search for Balance: Pharmaceuticals in Sri Lanka*. The Journal of The Dag Hammarskjöld Foundation. ZED Books, London.

101. K.A. Bashrahil (2010) Indicators of rational drug use and health services in Hadramout, Yemen. *Eastern Mediterranean Health Journal*. Vol. 16 No.2. Hadramout, Yemen.

102. Kafuko J, Bagenda D (1994) Impact of national standard treatment guidelines on rational drug use in Uganda health facilities. Kampala: Unicef/Uganda.

103. Kaiser Family Foundation Medicaid Facts (2009) Available at: http://www.kff.org. Accessed November 13, 2014

104. Kannan KP et.al (1991) Health and Development in Rural Kerala, Kerala Shastra Sahitya Parishad, Trivandrum.

105. Kannan KP et.al. (1991) Health and Development in Rural Kerala, Kerala Shastra Sahitya Parishad, Trivandrum
106. Kartar Singh Committee (1973) Committee on Multipurpose Worker under Health and Family Planning, MoHFW, New Delhi
107. Ke Xu et al. (2003) Household catastrophic health expenditure: a multicountry analysis. Lancet, (362): pp111–7
108. Kerry Wilbur, Amna Fadul and, and Hala Sonallah (2011) Pharmacovigilance in the Middle East. Qatar Foundation Annual Research Forum Proceedings 2011, BMP6
109. Kevan Wind (2010) The Management of the Procurement of Medicines For Secondary Care NHS Trust in England. NHS. Great Britain.
110. Kronfol NM (2012) Health services to groups with special needs in the Arab world: a review. Eastern Mediterranean Health Journal, 18:1247–1253
111. Kuna (2013) Kuwait health budget doubles but services not satisfactory' 'Economics play key role in healthcare' Arab Times Newspaper. 13/09/2013. 4p. Kuwait
112. Kuwait MOH (2010) An overview of Kuwait's national accreditation program. August 24, 2010. Quality & Accreditation Directorate Blog. Available from: http://qadkuwait.wordpress.com/2010/08/24/overview-of-kuwaits-national-accreditation-program/
113. Kvale, Steinar (1996) Interviews an Introduction to Qualitative Research Interviewing, Sage Publications,
114. Laing R, Hogerzeil, Ross-Degnan D (2001) Ten recommendations to improve use of medicines in developing countries. Health Policy Plan 2001, 16(1): 13-20
115. Laing RO. (2001) Final Comments on Updating and Disseminating the WHO Model List of Essential Drugs: the way forward revised version 10 September 2001. Geneva: World Health Organization. WHO.
116. Lall, S., and Bibile, S (1978) 'The political economy of controlling transnationals: the pharmaceutical industry in Sri Lanka (1972–76)' which appeared in *World De- velopment,* 1977, 5, pp. 677–98; *International Journal of Health Services,* 1978, 8(2), pp. 299–328;

Economic and Political Weekly, Sameeksha Trust, 1977, 12 (33/4), pp. 1419–36.

117. Le Grand A (1999) Intervention research in rational use of drugs: a review. *Health Policy and Planning*. 1999, 14(2):89-102.
118. Leah Hyslop (2010) Qatar population booms as economy grows. *The Telegraph*. UK.
119. Lexchin J, Mintzes B (2008) Medicine reimbursement recommendations in Canada, Australia, and Scotland. *The American journal of managed care*.;14 (9): 581-88.
120. Lincoln, Y. S., & Guba, E. G. (1985) *Naturalistic inquiry.* Beverly Hills, CA: Sage.
121. Linda Hantrais (1995) Comparative Research Methods. University of Surry. United Kingdom.
122. Linda Hantrais. (1995) Social Research Update. University of Surry. Surry. United Kingdom.
123. Lipton HL, Gross DJ, Stebbins MR, Syed LH. (2000) Managing the pharmacy benefit in Medicare HMOs: what do we really know? Health Affairs;(19): pp42-58.
124. Lohr, Sharon L. (1999) Sampling: Design and Analysis. Duxbury Press. USA
125. M. Healy and C. Perry (2000) *Qualitative Market Research: An International Journal* Volume 3. Number 3. 2000. pp. 118±126 # MCB University Press. ISSN 1352-275
126. Malak Makki (2014) New study reports on health challenges in Arab world. Translated by Rani Geha. Beirut. Lebanon. accessible through: http://www.al-monitor.com/pulse/security/2014/01/study-lancet-state-health-arab-world.html#ixzz49UvfvJVT
127. Management Sciences for Health (2012) National Medicine Policy. MSH/WHO accessible through http://apps.who.int/medicinedocs/documents/s19581en/s19581en.pdf
128. Marit Andrew, Bjørn Jøldal and Göran Tomson (1995) Norway's National Drug Policy Its Evolution and Lessons for the Future. *The Journal of The Dag Hammarskjöld Foundation.*

129. Mary Murray (1995) Australian National Drug Policies: Facilitating or Fragmenting Health? 1995. Australia.
130. McKinsey & Company. Serving Clients in the Middle East; Public sector. http://www.mckinsey.com/locations/middleeast/ourwork/servingclient/publicsector.aspx
131. McNamara, Carter, PhD (1999) General Guidelines for Conducting Interviews, Minnesota. USA.
132. McPake B, Hanson K, Mills A (no date) Community Financing of Health care in Africa: an evaluation of Bamako Initiative. *Social Science and Medicine*, 1933. 36(11):1383-1395.
133. MediLexicon, (2015) online Medical Dictionary. MediLexicon International Ltd. Bexhill-on-Sea, UK. Found through http://www.medilexicon.com/medicaldictionary.php?t=19778
134. Micovic P (1984) Health planning and management glossary. New Delhi, World Health Organization, Regional Office for South-East Asia.
135. Miles, MB. & Huberman, AM (1994) Qualitative Data Analysis (2nd edition). Thousand Oaks, CA: Sage Publications.
136. Ministerial Committee on Drug Policy (2007) National Drug Policy 2007–2012. Wellington: Ministry of Health.
137. Ministry of Finance. (2004) Jordan Public Expenditure Study. Health Sector Draft Report. Jordan Ministry of Finance publications.
138. Ministry of Finance. (2006) Jordan Public Expenditure Review, Jordan Ministry of Finance publications. (Arabic)
139. Ministry of Health (2009) Health Related Division, Kingdom of Saudi Arabia, www.moh.gov.sa
140. Ministry of Health (2009) Health Related Division, Kingdom of Saudi Arabia, www.moh.gov.sa
141. Ministry of Health Formulary, Drug List, (Revised Edition 2012), available online at http://www.moh.gov.sa/Portal/WhatsNew/Documents/MOHF_DRUG_LIST_CD.pdf, accessed 17- 04-2012.
142. Ministry of Health, Ghana, (2004) National Drug Policy. Second Edition.
143. Ministry of Social Development. (2002) Poverty Alleviation for a stronger Jordan: a comprehensive national strategy.

144. MoHFW (1983) National Health Policy, Govt. of India, Ministry of Health & Family Welfare, New Delhi
145. Mr Enrico Cinnella. (2009) Monitoring and Assessing Pharmaceutical Policies WHO/EMP, Geneva.
146. Murray Aitken (2015) Understanding the Role and Use of Essential Medicines Lists. The IMS Institute for Healthcare Informatics. Parsippany, USA.
147. My Little Norway (2009) Healthcare is NOT Free in Norway. Accessible through http://mylittlenorway.com/2013/12/healthcare-in-not-free-in-norway/
148. National essential drug list (1996) General Directorate of Pharmaceutical Services and Medical Supplies. Sana'a, Yemen, Ministry of Public Health.
149. NCAER (1991) Household Survey of Medical Care, National Council for Applied Economic Research, New Delhi. India.
150. Neuman, L. W. (2000) *Social Research Methods: Qualitative and Quantitative Approaches (4th Ed.)*, USA: Allyn and Bacon.
151. NICE, National Institute for Health and Care Excellence web site (2013) http://www.nice.org.uk/aboutnice/whatwedo/aboutclinicalguidelines/about_clinical_guidelines.jsp
152. Norway Ministry of Finance (2012) National Budget 2012. Norway. Accessible through http://www.statsbudsjettet.no/Statsbudsjettet-2012/English/
153. Norwegian Medicines Agency (2016) The Norwegian health care system and pharmaceutical system. Norway. Accessible through: http://www.legemiddelverket.no/english/the-norwegian-health-care-system-and-pharmaceutical-system/sider/default.aspx
154. NSS (1987) Morbidity and Utilisation of Medical Services, 42nd Round, Report No. 384, National Sample Survey Organisation, New Delhi. India.
155. OECD (2011) Health at a Glance 2011: OECD Indicators, OECD Publishing. http://dx.doi.org/10.1787/health_glance-2011-en
156. OECD (2014), OECD Reviews of Health Care Quality: Norway 2014: Raising Standards, OECD Publishing. http://dx.doi.org/10.1787/9789264208469-en

157. Ogunbekun I, Adeyi O, Wouters A Et al (1996) Cost and Financing of Improvements in the quality of maternal Health Services through the Bamako Initiative. Nigeria. *Health Policy and Planning*, 11(4):369-384.
158. Oman MOH (2000) Oman National Drug Policy. Muscat. Oman.
159. Oman State Budget News alert (2016) Economic developments in Oman from Tax and Legal Services Middle East. Oman. Accessible through: https://www.pwc.com/m1/en/tax/documents/2016/oman-2016-budget-newsalert.pdf
160. Philip Burnard PhD (2004) Writing a qualitative research report, Accident and Emergency Nursing (12), pp176–181. UK
161. Powell-Jackson T, Basu S, Balabanova D, McKee M, Stuckler D (2011) Democracy and growth in divided societies: a health-inequality trap? *Soc Sci Med* 2011; **73:** 33–41.
162. Praful Bidwai (1995) One Step Forward, Many Steps Back Dismemberment of India's National Drug Policy. Development Dialogue 1995:1. *The Journal of The Dag Hammarskjold Foundation*. India.
163. Productivity Commission (2003) Evaluation of the pharmaceutical industry investment program. Productivity Commission: Canberra.
164. Prof. Saleh Bawazir (2012) Saudi Arabia Pharmaceutical Country Profile. The Saudi Food and Drug Authority in collaboration with the World Health Organization. Riyadh. Saudi Arabia.
165. R. Duggal (2011) Evolution of Health Policy in India, CEHAT, India.
166. R. Laing, B. Waning, A. Grey, N. FordE. Hoen, (2003) “25 Years of the WHO Essential Medicines Lists: Progress and Challenges”, *the Lancet.*
167. Raftery JP (2008) Paying for costly pharmaceuticals: regulation of new drugs in Australia, England and New Zealand. *Med J Aust* 2008; 188:26-8.
168. Ragin, C. (1987) The comparative method. Berkeley: University of California Press
169. Ramanathan, R (2008) “The Role of Organizational Change Management in Offshore Outsourcing of Information Technology Services” Universal Publishers.
170. Regional Office for Europe (1998) A glossary of technical terms on the economics and finance of health services. World Health Organization,

Available at:
http://www.euro.who.int/__data/assets/pdf_file/0014/102173/E69927.pdf

171. Report of an Expert Committee on the Selection of Essential Drugs (1977) Geneva: World Health Organization.
172. Report on National Consultative Meeting on Drug Policies and Management (1988) Department of Health, Colombo
173. Report on the 12th Expert Committee on the Selection and Use of Essential Medicines (2002) Geneva: World Health Organization.
174. Rianne van den Ham (2009) Selection of Essential Medicines – a background paper for the World Medicines Situation 2010 report. WHO Collaborating Centre for Pharmacoepidemiology & Pharmaceutical Policy Analysis. University of Utrecht. WHO. Geneva. Switzerland.
175. Richard Laing and Klara Tisocki (2004) how to develop a national formulary based on the WHO model formulary, a Practical Guide. WHO. Geneva. Switzerland.
176. Richard Laing. *Contact* n°187 – January - May 2009. Geneva, Switzerland
177. Rietveld AH, Haaijer-Ruskamp FM (2002) Policy options for cost containment of pharmaceuticals. In: Dukes MNG, Haaijer-Ruskamp FM, De Joncheere CP, Rietvel AH (eds). Drugs and Money—Prices, Affordability and Cost Containment. 7th edn. Amsterdam, the Netherlands: IOS Press, pp. 29–54.
178. Ritchie J et al, (2014) Qualitative Research Practice; guide for Social Sciences and Research. 2nd Edition. Sage publication, London. UK
179. Robin Gauld (2009) the new Health Policy, Open University Press. England.
180. Robson, Colin (2002) Real World Research. A Resource for Social Scientists and Practitioner-Researchers (Second Edition). Malden: Blackwell. p. 624.
181. S.N. (2012) "Gulf Cooperation Council". Deutsch Federal Foreign Office. Available from: http://www.auswaertiges-amt.de/EN/Aussenpolitik/RegionaleSchwerpunkte/NaherMittlererOsten/GCC/Uebersicht.html (accessed April 2013)

182. S.N. (2012) Trading economics, available from: http://www.tradingeconomics.com/bahrain/health-expenditure-public-percent-of-government-expenditure-wb-data.html.
183. S.N. (2012) World Bank report published in 2012. World bank publications. Washington DC, United States. Available from: http://issuu.com/world.bank.publications/docs/annual_report_2012_en#
184. Sarkar, P. (2004). A rational drug policy. Indian Journal Of Medical Ethics, 1(1), 11 12. Retrieved from http://issuesinmedicalethics.org/index.php/ijme/article/view/770/1843
185. Savedoff, W.D. (2007) What Should a Country Spend on Health Care? Health Affairs 26, (no. 4) pp 962–970; 10.1377/hlthaff.26.4.962
186. SCRIP (1994) No 1974:21. Geneva: World Health Organisation.
187. Seiter, A. (2010) A Practical Approach to Pharmaceutical Policy, World Bank, p. 47.
188. Siem, H (1986) Choices for Health. An Introduction to the Health Services in Norway, Universitetsfforlaget. Oslo.
189. Snieder, R & Larner, K (2009) The Art of Being a Scientist: A Guide for Graduate Students and their Mentors, Cambridge University Press.
190. Stafinski T, Menon D (2003) A Comparison of International Models for Common Drug Review Processes in publicly-funded Health Care Systems. Working Paper 03–09. ed. Institute of Health Economics ed. National Library Canada. Canada.
191. Standard Treatment Guidelines (2010) Ghana Ministry of Health. 6th Edition. Ghana, West Africa
192. Steinwachs, D (2005) Operations Research. Encyclopaedia of Biostatistics.
193. Steve Bojakowski, John Spoors (2013) The funding of orphan medicines in the UK. *British Journal of Healthcare Management* 2013 Vol 19 No 7
194. Suzanne R Hill (2012) Cost-effectiveness analysis for clinicians. BMC Medicine. 10:10. Accessible through: http://www.biomedcentral.com/1741-7015/10/10
195. SU Yasuda1, L Zhang2 and S-M Huang. 2008. The Role of Ethnicity in Variability in Response to Drugs: Focus on Clinical Pharmacology Studies. *Clinical Pharmacology & Therapeutics* | Vol 84, No. 3, Maryland,

USA. Accessible through; http://www.fda.gov/downloads/Drugs/ScienceResearch/.../UCM085502.pdf

196. Sven Hamrell Olle Nordberg, Wendy Davies Jason Pearce, Ahmed Ben Salah, Just Faaland Joseph, Ki-Zerbo Marc Nerfin, Göran Ohlin Juan, Somavia (1995) Making National Drug Policies a Development Priority A Strategy Paper and Six Country Stories. Development dialogue 1995:1. *The Journal of The Dag Hammarskjöld Foundation.* Sweden.
197. Syed Rizwanuddin Ahmad (2014) Pharmacovigilance bolstered in the Arab world. *The lancet*. Vol 384. Dec13, 2014.
198. Terry Green and Salah Gammouh. (2012) Strategies to Improve the Use of Medicines—Standard Treatment Guidelines Review of the Cesarean-section Antibiotic Prophylaxis Program in Jordan and Workshop on Rational Medicine Use and Infection Control, Amman, Jordan, March 4-8, 2012
199. The Copenhagen declaration on health policy (1994) Copenhagen, World Health Organization, Regional Office for Europe, Available at: http://www.euro.who.int/__data/assets/pdf_file/0006/114936/E93948.pdf
200. The Expert Committee Report from 1977 and the Information to be included with an application for inclusion, change or deletion of a medicine in the WHO Model List of Essential Medicines in 2009. Geneva: WHO
201. The Interagency Pharmaceutical Coordination (IPC) Group (1999) Operational principles for good pharmaceutical procurement. Interagency document. Geneva: World Health Organization; WHO/EDM/PAR/99.5.
202. The king fund.2016. http://www.kingsfund.org.uk/projects/nhs-in-a-nutshell/nhs-budget?gclid=CIP35-D1pMsCFVYo0wodgJ8ORw
203. The Royal Borough of Windsor and Maidenhead (2010) Maidenhead, Berkshire. UK. Link can be found: http://www.rbwm.gov.uk/web/meetings_declaring_interests_guidance.htm#
204. The World Bank (2015) USA. http://www.worldbank.org/en/country
205. The world medicines situation. Geneva, World Health Organization (2004) (WHO/EDM/PAR/2004.5)

(http://www.cdf.sld.cu/World_Medicines_Situation.pdf, accessed 2 December 2007).

206. Tony Waddell (2010) World Health Statistics 2010. *WHO*. Geneva. Switzerland.

207. Treece, E. W. & Treece, J. W. (1982) Elements of research in nursing (3rd ed.). St. Louis, MO: Mosby.

208. US Department of Health (2008) The World Health Organisation. http://www.allcountries.org/health/essential_medicines_list_eml.html

209. Van Belle, G. (2002) Statistical rules of thumb. New York: John Wiley.

210. Venulet J. (1977) The WHO Drug Monitoring Programme: The formative years (1968-1975)

211. Walley T, Earl-Slater A, Haycox A, Bagust A (2000) an integrated national Pharmaceutical policy for the United Kingdom? *BMJ 2000*, 321(7275): 1523-6

212. Weerasuriya, (1990) Drug Utilization from 1987 to 1989 in the Sri Lankan Public Health Sector'

213. WHA (1979) Action programme on essential drugs, WHA32.41.

214. White, B (2005) Writing your MBA dissertation. London: Thomason Learning.

215. WHO (1979) *the Selection of Essential Drugs,* Technical Report Series 641, World Health Organisation, Geneva.

216. WHO (1987) "The Rational Use of Drugs - Report of the Conference of Experts, Nairobi 25-29 November 1985". Available: http://apps.who.int/medicinedocs/en/d/Js17054e/

217. WHO (1999) Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies: Interagency Guidelines © World Health Organization 1999

218. WHO (2001) How to develop and implement a national drug policy. 2nd Edition. WHO. Geneva.

219. WHO (2002) The Importance of Pharmacovigilance; Safety Monitoring of medicinal products. Geneva. Switzerland.

220. WHO (2002) The Selection of Essential Medicines - WHO Policy Perspectives on Medicines, No. 004, June 2002. Geneva. WHO.

221. WHO (2003) Annual Report 2002 – Essential Drugs and Medicines Policy: Supporting Countries to close the access gap. Geneva. Switzerland.
222. WHO (2003) *How to develop and implement a national drug policy, in WHO Policy prospective on medicines.* Geneva: world Health Organisation; Available at: http://apps.who.int/medicinedocs/eh/d/Js4869e/.
223. WHO (2003) Introduction to Drug Utilization Research. Geneva. Switzerland
224. WHO (2004) Country Cooperation Strategy for WHO and the State of Kuwait 2005–2009. Geneva. WHO. Accessible through; http://www.who.int/countryfocus/cooperation_strategy/ccs_kwt_en.pdf
225. WHO (2004) The essential medicines concept: from its beginnings until today, Geneva: WHO, WHO/EDM/2004.3, p. 1
226. WHO (2004) The world medicine situation. Geneva. 2004. http://apps.who.int/medicinedocs/en/d/Js6160e/8.html
227. WHO (2005) The Health and Environment Linkages Initiative. Legislation and regulation. Geneva, World Health Organisation.
228. WHO (2006) Constitution of the World Health Organization, Basic Documents, Forty-fifth edition, Geneva. Switzerland.
229. WHO (2006) Measuring Transparency in Medicines Registration, Selection and Procurement – Four Country Assessment Studies, WHO, p. 1. Geneva.
230. WHO (2006) Regional Health System Observatory, Geneva. WHO.
231. WHO (2007) Constitution of the World Health Organization. 45th Edition. Geneva. Switzerland.
232. WHO (2007) Level 1 Survey, Geneva Switzerland.
233. WHO (2008) “Backgrounder and Facts for Launch of the United Nations Report Delivering on the Global Partnerships for Achieving the Millennium Development Goals. Geneva. Switzerland.
234. WHO (2009) “Continuity and Change – Implementing the Third Who Medicines Strategy 2008 m-2013”.
235. WHO (2010) Country Cooperation Strategy for WHO and Bahrain 2005–2010, Geneva. WHO.

236. WHO (2010) Country Health Information Profile. Accessible through; http://www.wpro.who.int/countries/aus/2AUSpro2011_finaldraft.pdf?ua=1
237. WHO (2010) Country Health Information Profile. Accessible through; http://www.wpro.who.int/countries/aus/2AUSpro2011_finaldraft.pdf?ua=1
238. WHO (2013) “WHO Model List of Essential Medicines: 18th list”
239. WHO (2013) Country Cooperation Strategy for WHO and Jordan 2008–2013, Geneva.
240. WHO (2013) Essential Medicine List. Geneva. Switzerland.
241. WHO (2013) Kuwait: WHO Statistical Profile. Geneva. Switzerland.
242. WHO (2014) Glossary. Geneva. http://www.who.int/healthsystems/hss_glossary/en/index5.html
243. WHO (2014) World Health Statistics. Geneva. Switzerland.
244. WHO (2015) 20th Expert Committee: Expert review. 2015. Geneva. Switzerland. http://www.who.int/selection_medicines/committees/expert/20/reviews/en/
245. WHO (2015) Essential medicines selection; National Medicines List/Formulary/Standard Treatment Guidelines. 2015. Geneva. Switzerland. www.who.int/selection_medicines/country_lists/en/#top
246. WHO (2015) Good Governance for Medicines (GGM). Geneva. Switzerland. http://www.who.int/medicines/ggm/en/#
247. WHO (2015) Policy and legal Framework. Geneva. Switzerland accessible through http://apps.who.int/medicinedocs/documents/s19581en/s19581en.pdf
248. WHO (2015) rational drug use. Accessible through; http://www.who.int/medicines/areas/rational_use/en/
249. WHO (2015) Why is good governance relevant to the pharmaceutical public sector? Geneva. Switzerland. Accessible through http://www.who.int/medicines/areas/policy/goodgovernance/why/en/
250. WHO (2016) Health Promotion. Geneva. Switzerland. Accessible through http://www.who.int/healthpromotion/about/goals/en/
251. WHO and health action international (2008) Measuring Medicines prices, availability, affordability and price components, 2nd edition. Geneva

252. WHO Executive Board (2001) WHO medicines strategy: Revised procedure for updating WHO's Model List of Essential Drugs. 109th Session. Geneva.
253. WHO Executive Board 124th Session. 4 December 2008. Progress reports Report by the Secretariat. Geneva. Switzerland.
254. WHO HAI (2008) Medicine prices and access to medicines in the Eastern Mediterranean Region. Geneva. Switzerland. http://www.haiweb.org/medicineprices/surveys/200404MA/sdocs/survey%20summary%20report.pdf
255. WHO medicines strategy 2004–2007 (2004) Geneva, World Health Organization, 2004 (WHO/EDM/2004.5)
256. WHO, (2004). Country Cooperation Strategy for WHO and the State of Kuwait 2005–2009. Geneva. WHO. Available from: http://www.who.int/countryfocus/cooperation_strategy/ccs_kwt_en.pdf
257. WHO. (2006), Regional Health System Observatory, Geneva. WHO.
258. World Investment Report (2007) Transnational Corporations, Extractive Industries and Development. unctad.org/en/docs/wir2007p4_en.pdf
259. Worldatlas (2015) Bahrain. http://www.worldatlas.com/webimage/countrys/asia/bh.htm
260. Xingzhu Liu (2003) Policy Tools for Allocative Efficiency of Health Services. WHO Library Cataloguing-in-Publication Data. Geneva. Switzerland.
261. Y. Neyaz, N.A. Qureshi,T. Khoja, M.A. Magzoub, A. Haycox and T. Walley. (2011) Medication prescribing pattern in primary care in Riyadh city, Saudi Arabia. EMHJ, 17 No. 2;149-155.
262. Yousef Almahdi (2015) State of Kuwait; Overview of the Healthcare Sector. International trade Administration. U.S. Embassy. Kuwait.
263. Zafrullah Chowdhury (1995) Bangladesh: A Tough Battle for a National Drug Policy. Development Dialogue 1995:1 *The Journal of The Dag Hammarskjöld Foundation*. ZED Books, London.
264. Zainab Calcuttawala (2016) Kuwait to Increase Fuel Prices By Up To 80 Percent In September. *OilPrices.com*. accessible through:

Appendices

Appendix I

Consent form for participating in the Questionnaires

CONSENT FORM

Establishing an essential Medicine List at the state of Kuwait

Nadyah Alayadhi
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University of Bradford
Richmond building
BD7 1DP

		Please Initial Box
1.	I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.	☐
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving reason.	☐
3.	I agree to take part in the above study.	☐

Name of Participant	Date	Signature
Name of Researcher	Date	Signature

Appendix II

Assessments of the current medicine supply system in the State of Kuwait, and the medicines regulatory system. Healthcare providers views on the concept of Essential Medicines list

Assessments of the current medicine supply system in the State of Kuwait, and the medicines regulatory system.
Healthcare providers views on the concept of Essential Medicines list

The purpose of the study is to measure the current medicines supply system and what visions healthcare providers might have toward having an Essential Medicine List. This study forms part of PhD research programme in developments, economic studies and pharmaceutical innovations, which is under the supervision of Dr John Lawler and Prof B.J. Clark, University of Bradford, UK.

- Please complete the questionnaire and return it to me in the sealed envelope provided.
- All responses will be dealt with strict confidence and anonymously.
- please direct questions or comments to

Nadyah Alayadhi
SISS and School of Life Sciences
University of Bradford
Bradford, West Yorkshire, UK
n.y.alayad@student.bradford.ac.uk.

1. **Demographic data**

1.1 How long have you been working as a healthcare provider?

- 1-5 years
- 6-10 years
- 11 years and over

1.2 Speciality

- Physicians
- Academic staff (university, PAAET)
- CMS staff
- Public Pharmacists
- Private Pharmacist
- Legal Staff

2. **Medicine supply system**

2.1 Are you satisfied with the current medicine supply system?

- Yes
- No
- No Comment

2.2 Do you think the medicine supply system is well regulated?

- No
- Appropriately regulated
- Room for improvement
- No comment

2.3 In your own words, how do you think the medicine supply system can be improved?

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3. Generic Medicines

3.1 If a generic drug has proven to have good quality and efficacy, to what extent would you prescribe it?

- Always prescribe it
- Prescribe it, if the patient happy to take it
- Prescribe it, if no brand available
- Prescribe it, some of the times
- Never prescribe it
- Don't Know

4. Essential Medicine List

The WHO essential medicine list defined as " drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford." it has been adopted by over 150 countries worldwide.

4.1 What are your views on the establishment of 'Essential Medicine List' program at the state of Kuwait?

- I would strongly agree with its establishing
- I would agree with its establishing
- I have no strong feelings either way
- I would disagree with its establishing
- I would strongly disagree with its establishing

Comments……
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Appendix III

Assessment of the availability of Standard treatment guidelines in Kuwait healthcare facilities

Assessment of the availability of Standard treatment guidelines in Kuwait healthcare facilities

The purpose of the study is to measure the current medicines supply system and what visions healthcare providers might have toward having an Essential Medicine List. This study forms part of PhD research programme in developments, economic studies and pharmaceutical innovations, which is under the supervision of Prof B.J. Clark and Dr John Lawler, University of Bradford, UK.

- Please complete the questionnaire and return it to me in the sealed envelope provided
- All responses will be dealt with strict confidence
- Please direct questions or comments to

Nadyah Alayadhi
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Bradford, West Yorkshire, UK
n.y.alayad@student.bradford.ac.uk.

Healthcare facility type

- Primary healthcare facility
- Secondary healthcare facility
- Tertiary healthcare facility

Duration of work experience at current healthcare facility.

- 1-5 years
- 6-10 years
- 11 years and over

Are you aware of the Standard Treatments Guidelines of your centre?

- Yes
- No
- Not sure
- Briefly

What type of STG do you use?

……
……
……

Are you using the same as your colleagues?

- Yes
- No
- Maybe
- Not sure

Why do you use this kind of STG?

- Learned at university.
- Conveyed from previous training at different country.
- The official guidelines used by current centre.
- Instructed by previous colleague to follow this STG.
- Others, (please specify)

  ……

  ……

  ……

  ……

Appendix IV

Point to be covered when meeting with Senior Health Managers

Name:

Position:

Date:

After Reading the information provided, do you understand the concept of Essential Medicine List programme?

What are your views?

- Concept:

- Feasibility:

- Gains:

- Drawbacks:

Would you like EML programme to be implemented in the state of Kuwait?

Would you like to be part of the process of executing EML?